



0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twelfth 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

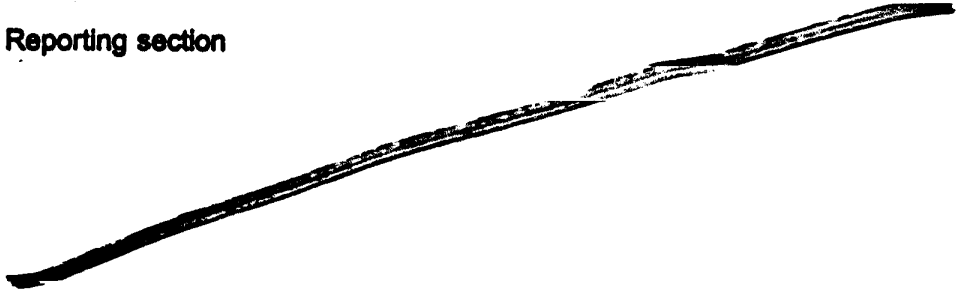


J. The Quality Control and Standards section

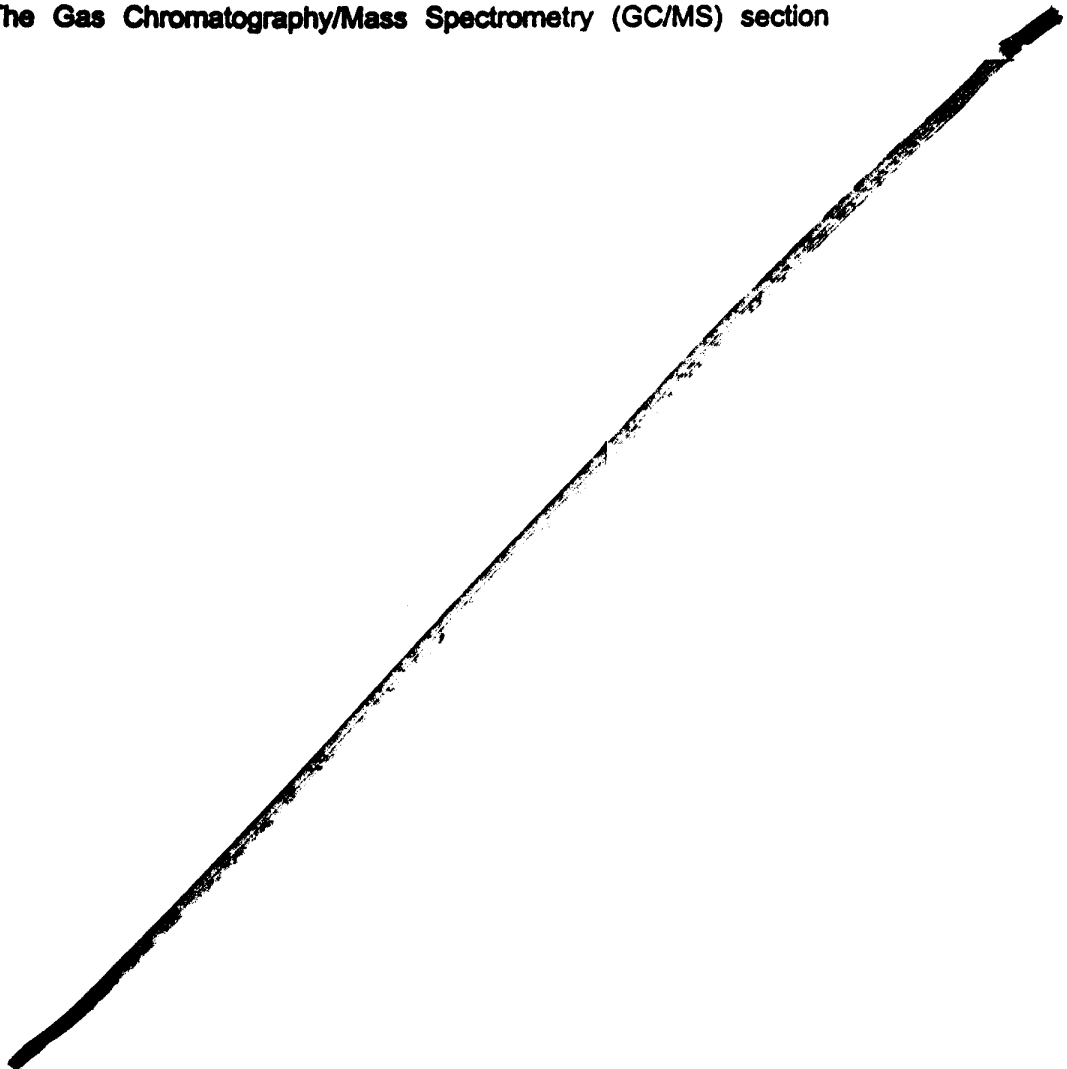




K. The Reporting section



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



Dr. Mathews
Page 3 of 3
12/07/98

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/M12


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0519
Document No. Final

Laboratory: Baptist Medical Center

Location: Little Rock, AR

Document Reviewed: Application Form
 Inspection Report #M12 Date: October 29, 1998
 Other _____

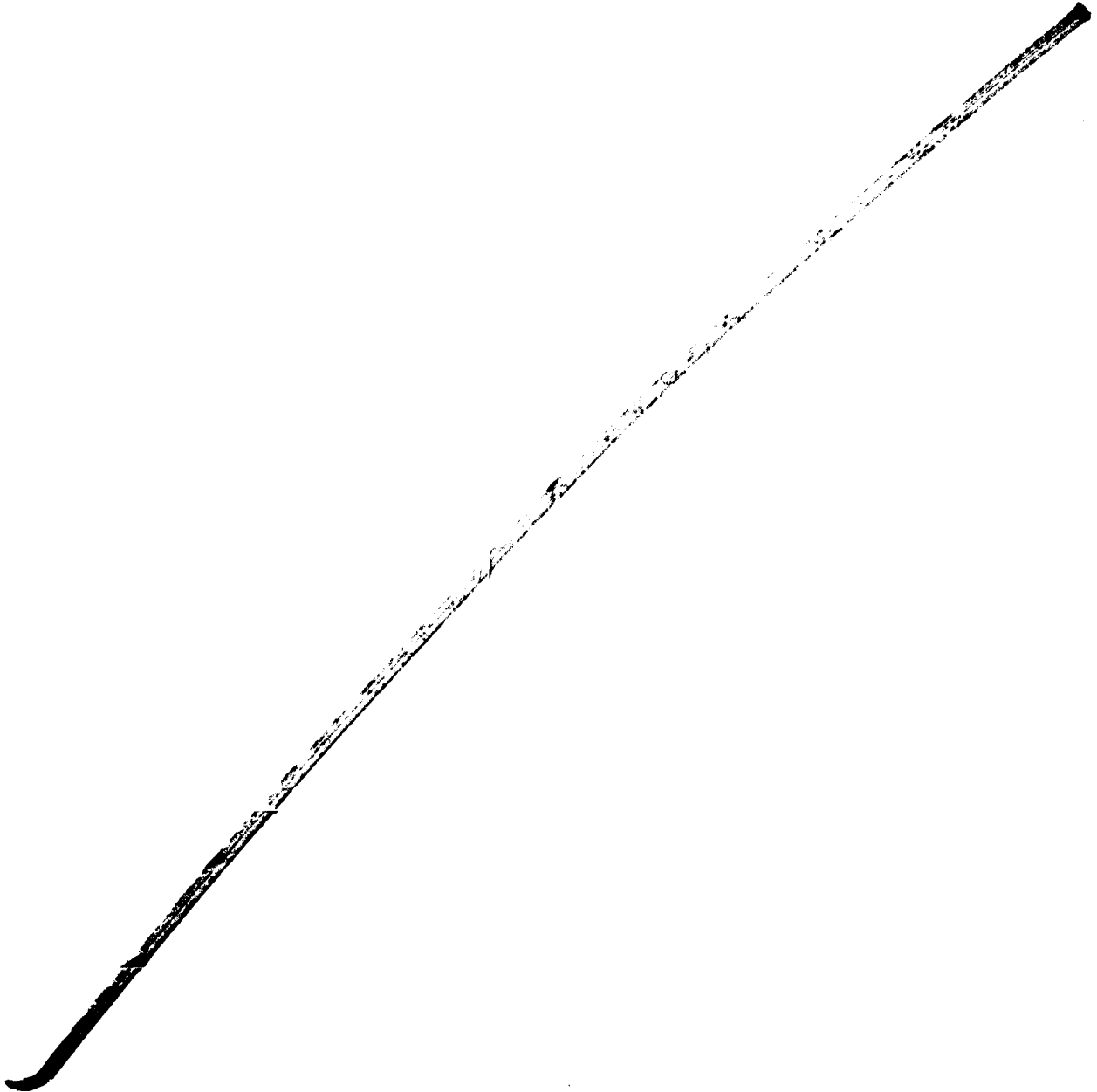
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



[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

Section M. Immunoassay

Section N. Gas Chromatography/Mass Spectrometry



Baptist
MEDICAL CENTER

115199 SDC

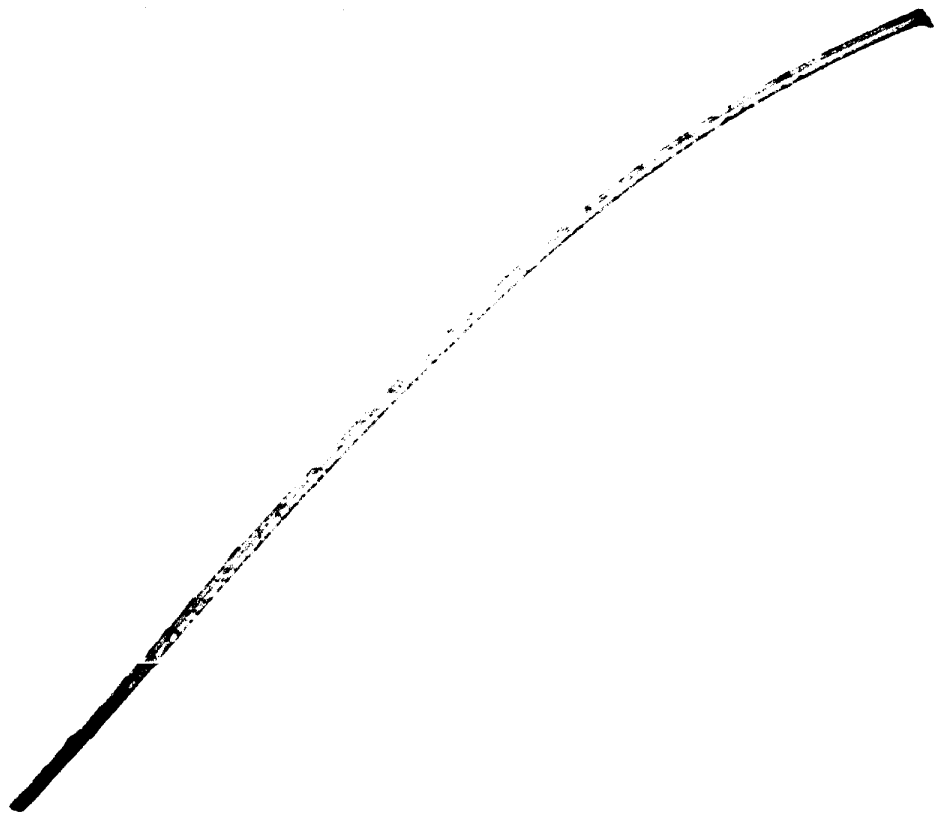
9601 Interstate 650, Exit 7
Little Rock, AR 72205-7299
501 202-2000

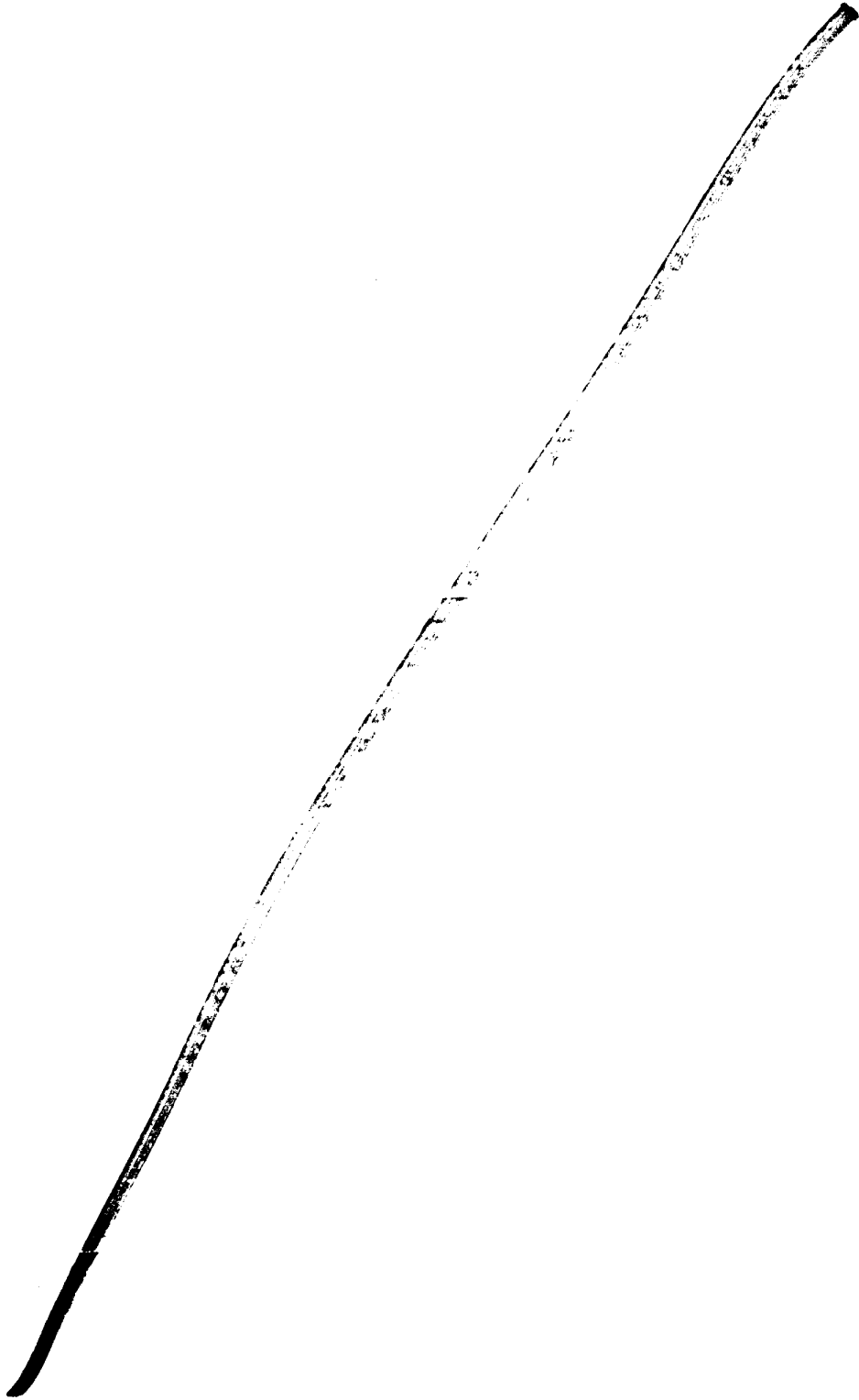
January 7, 1999

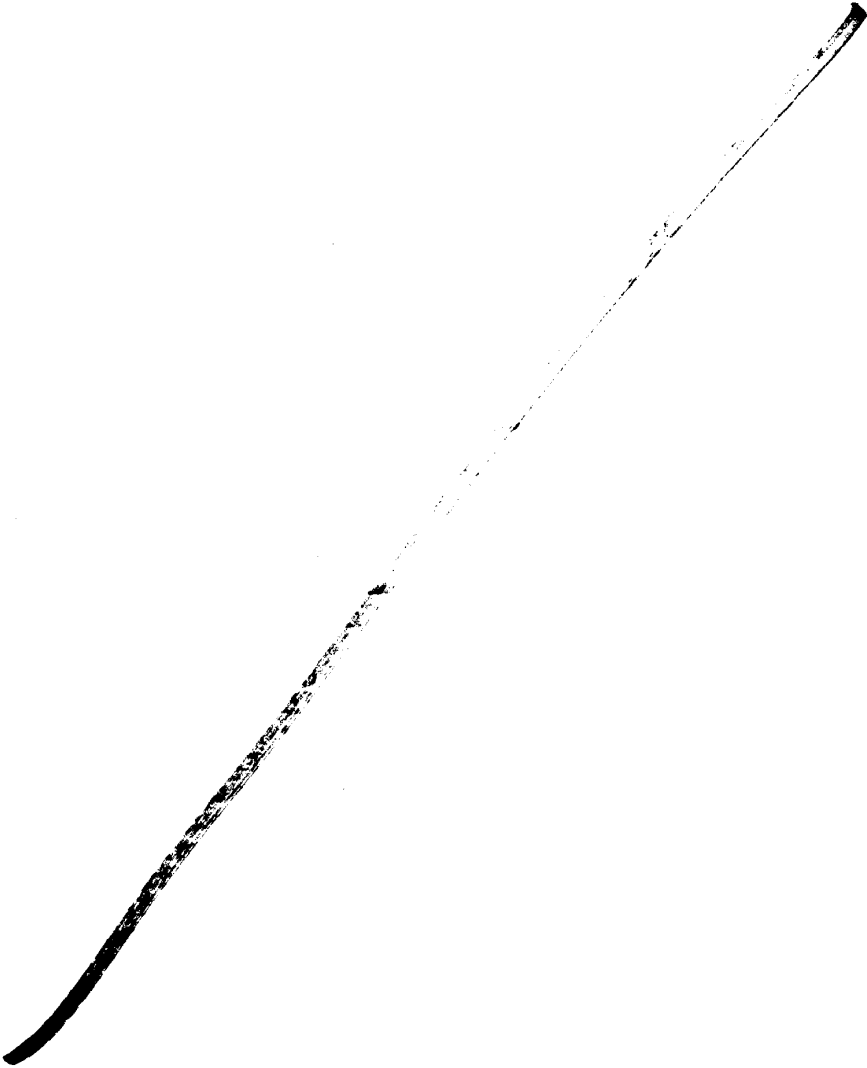
Ms. Susan Crumpton
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Crumpton:

Enclosed with this letter is our documentation of actions taken in response to your inspection critique dated December 7, 1998. I have organized the items to correspond with your summary.







If there are any questions or if additional documentation is needed, please contact me at 501-202-2783, and we will comply as expeditiously as possible.

Sincerely,



Samuel E. Mathews, Ph.D.
Responsible Person

RESEARCH TRIANGLE INSTITUTE



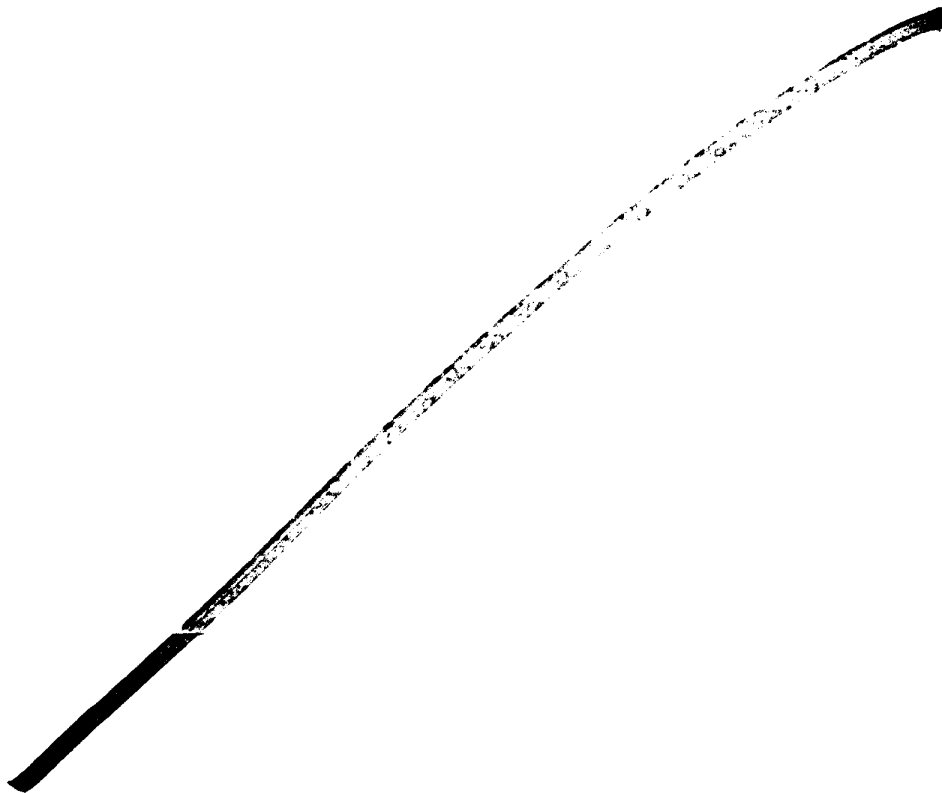
National Laboratory Certification Program

February 17, 1999


0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

We have reviewed the material submitted in your correspondence of January 7 and February 12, 1999, provided in final response to issues raised during the twelfth maintenance inspection of your laboratory as originally outlined in our correspondence of December 7, 1999. The following is a review of the material submitted:



Dr. Mathews
Page 2 of 2
02/17/99



The laboratory submitted some original training documents concerning revised SOPs. We have made copies for our records and are returning the originals to the laboratory.

Based upon our review of the material submitted, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory continue to be certified under the National Laboratory Certification Program (NLCP). All corrective actions must be implemented within 30 days of receipt of this correspondence and will be reviewed during the next inspection.

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

Sincerely,


Susan D. Crumpton
NLCP Inspection Analyst

cc: Project Files/M12



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

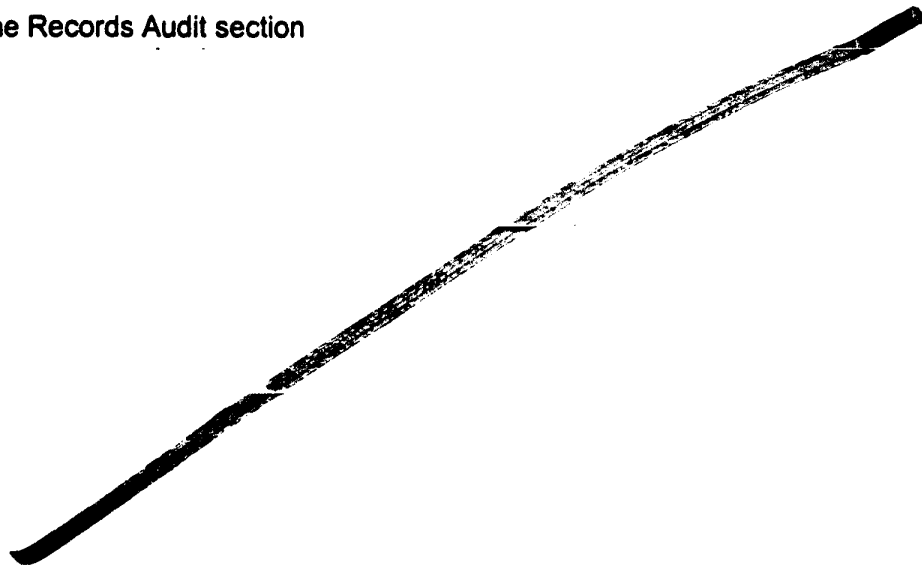
June 10, 1999

0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the thirteenth 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:

J. The Records Audit 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

Dr. Mathews
Page 2 of 2
06/10/99

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/M13


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0519
Document No. Fina

Laboratory: Baptist Medical Center—Toxicology Laboratory

Location: Little Rock, AR

Document Reviewed: Application Form
 Inspection Report #M13 Date: 29 April 1999
 Other _____

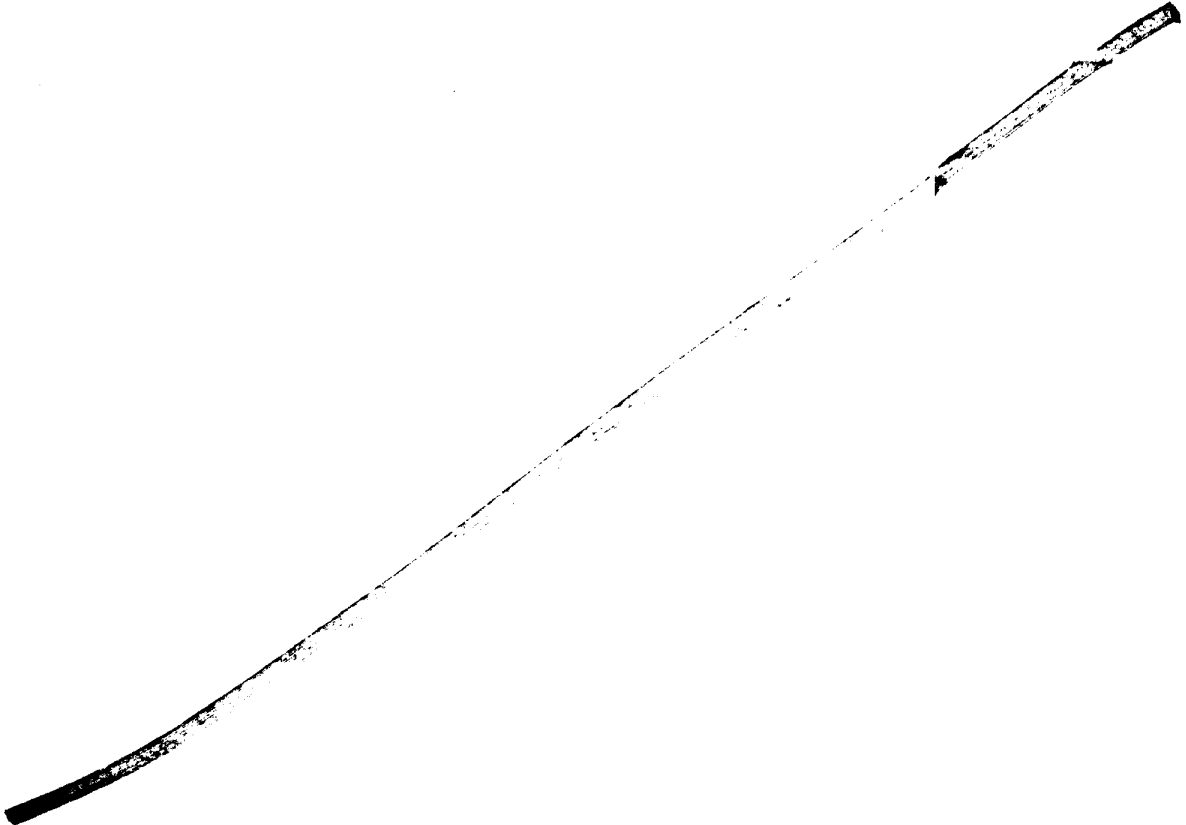
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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



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

[Large diagonal redaction]

Section K. Reporting

[Redacted]

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

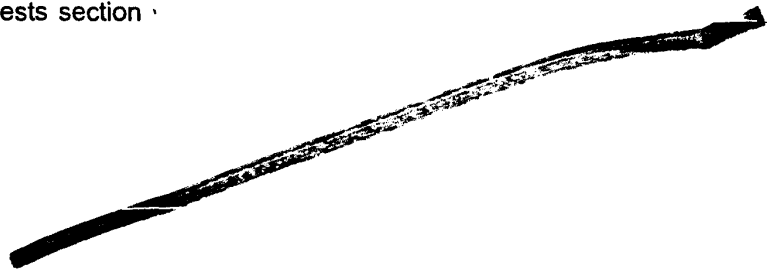
December 2, 1999

0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

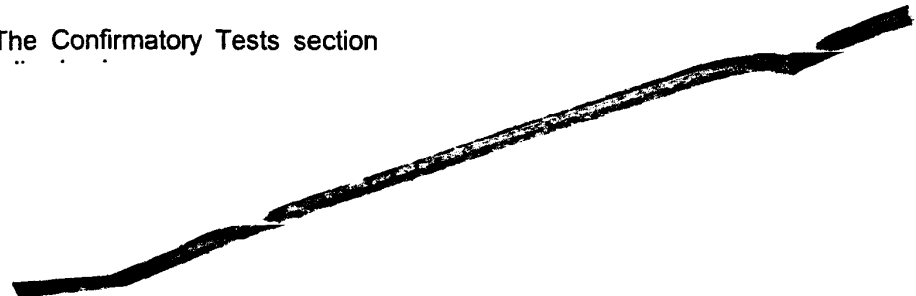
Dear Dr. Mathews

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fourteenth 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.

H. The Initial Tests section



I. The Confirmatory Tests section

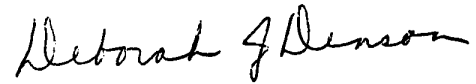


RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the 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.

Dr. Mathews
Page 2 of 2
12/02/99

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/M14


NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0519
Document No. Final

Laboratory: Baptist Medical Center—Toxicology Laboratory

Location: Little Rock, AR

Document Reviewed: Application Form
 Inspection Report #M14 Date: 28 October 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




Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel





RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

June 9, 2000

0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the fifteenth 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

A large, thick, black diagonal line redacting the content of the letter, covering the text from item E down to item H.

H. The Initial Tests section

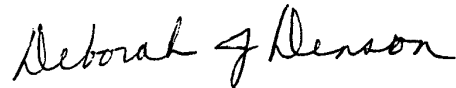
A thick, black diagonal line redacting the content of the letter, covering the text from item H down to the footer.

Dr. Mathews
June 9, 2000
Page 2 of 2

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/M15



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0519
Document No. Final

Laboratory: Baptist Medical Center—Toxicology Laboratory

Location: Little Rock, AR

Document Reviewed: Application Form
 Inspection Report #M15 Date: 27 April 2000
 Other _____

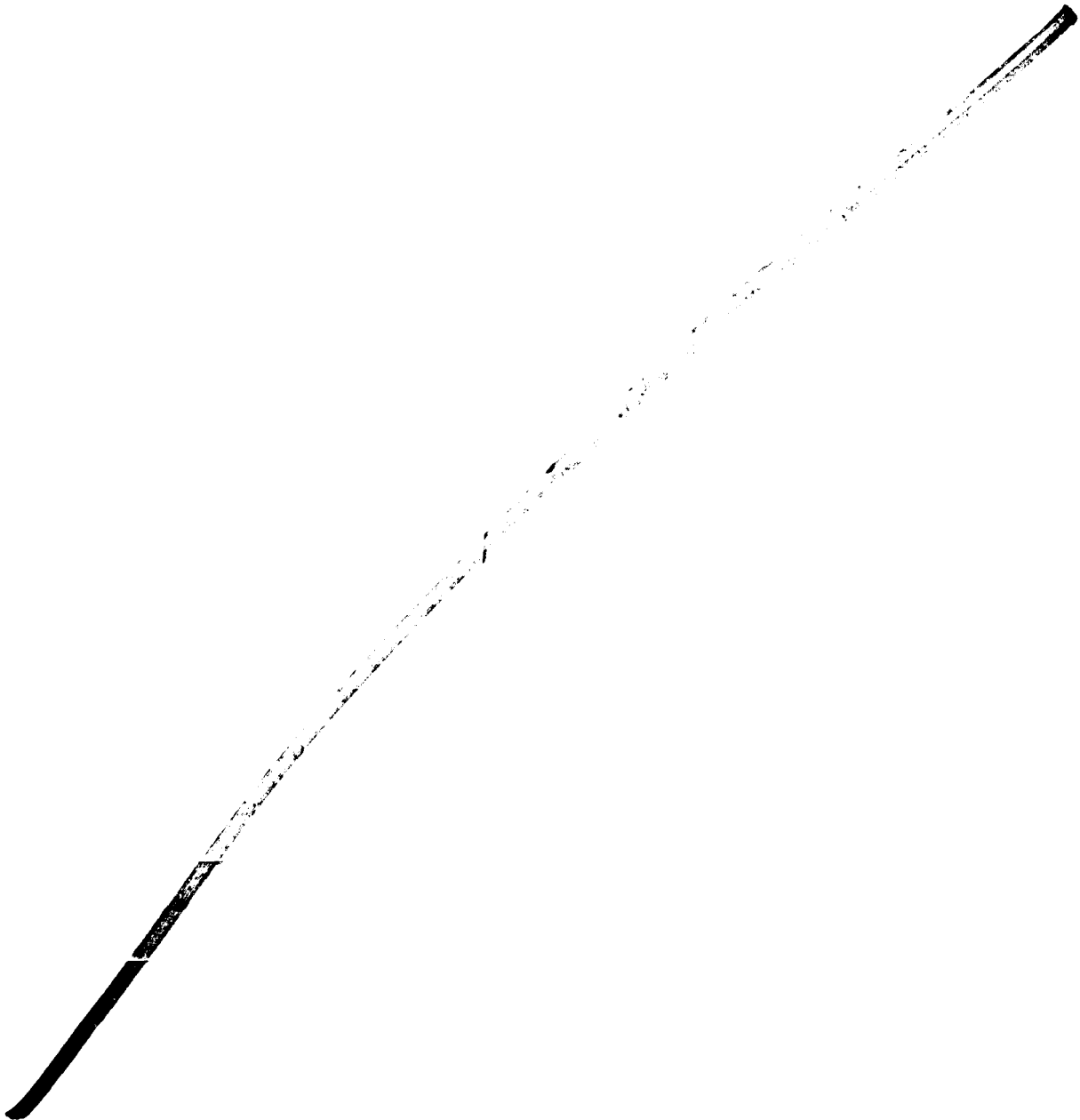
Status: Highly Acceptable Acceptable
 Unacceptable Failure

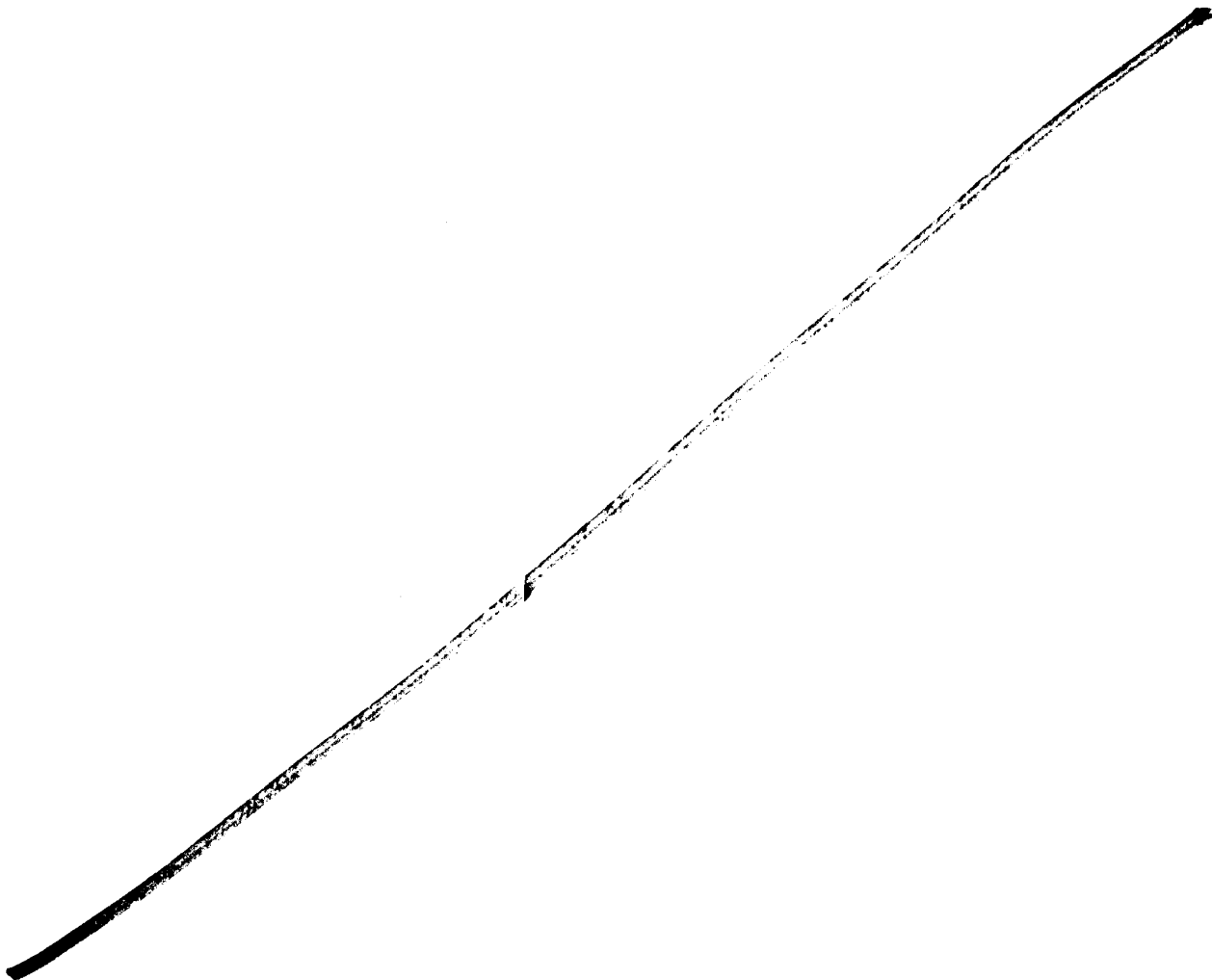
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

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



Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests



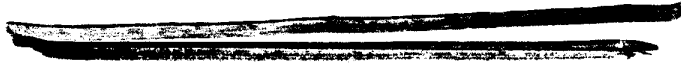
Section J. Records Audit



Section K. Reporting



Section L. Computers, Software, and LIMS



Section M. Equipment and Maintenance



Section N. Personnel



December 20, 2000

0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

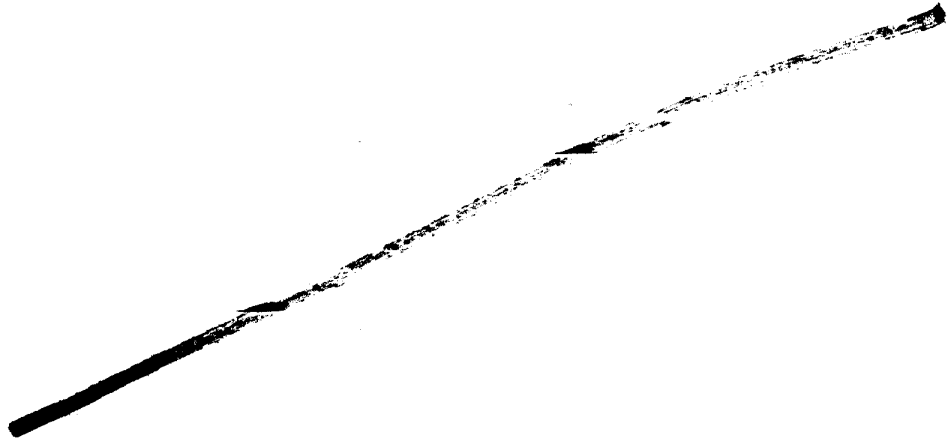
The enclosed critique was developed from the inspection reports of the inspectors who conducted the sixteenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is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

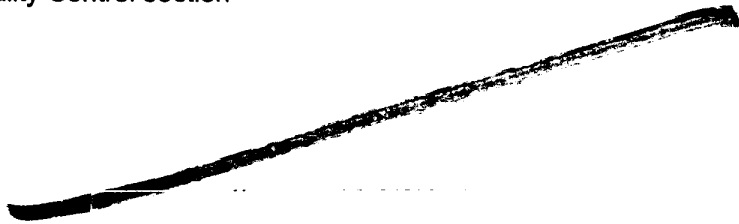


F. The Chain of Custody, Accessioning, and Security section





G. The Quality Control section



K. The Reporting section



N. The Personnel section



Dr. Mathews
December 20, 2000
Page 3 of 3

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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



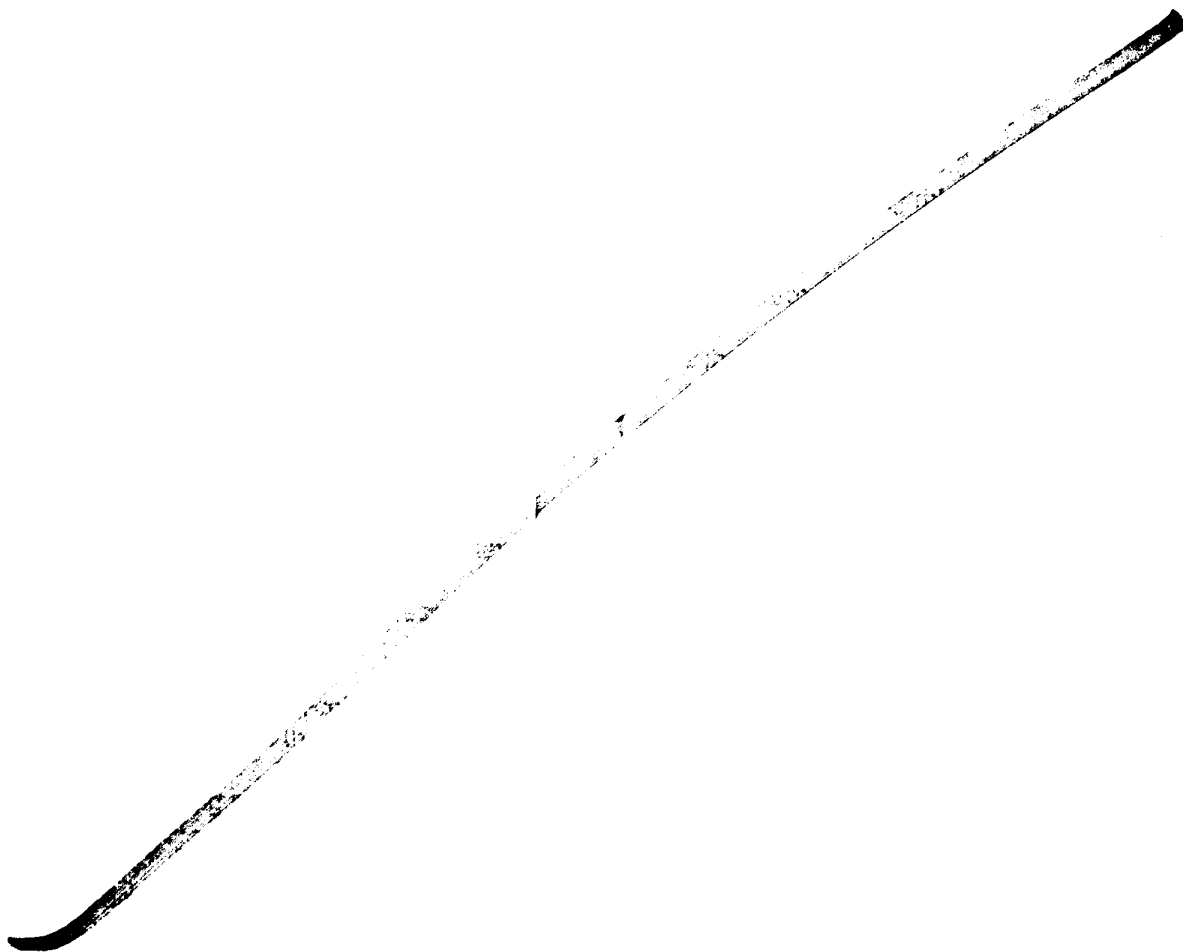
Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M16

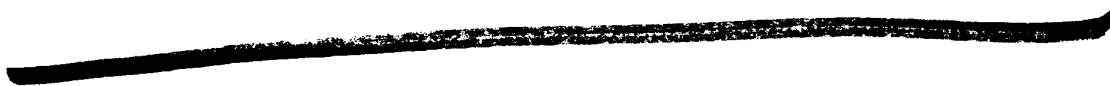


The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

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

[Redacted]

Section M. Equipment and Maintenance

[Redacted]

Section N. Personnel

[Redacted]

received
1/22/01 DN

Baptist
MEDICAL CENTER

9601 Interstate 630, Exit 7
Little Rock, AR 72205-7299
501 202-2000

January 20, 2001

Ms. Deborah J. Denson
NLCP/RTI
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Denson:

This letter is our response to the items listed in your letter to us of December 20, 2000, reviewing issues brought up in our sixteenth maintenance inspection. As requested in your letter, the responses listed here will be presented in the same order and labeled as in your communication.

If there are any additional questions or issues to be addressed, please do not hesitate to notify me at 501-202-2783 or at _____

Sincerely,

A handwritten signature in cursive script, appearing to read 'S. Mathews', written in black ink.

Samuel E. Mathews, Ph.D., DABCC
Responsible Person



RESEARCH TRIANGLE INSTITUTE

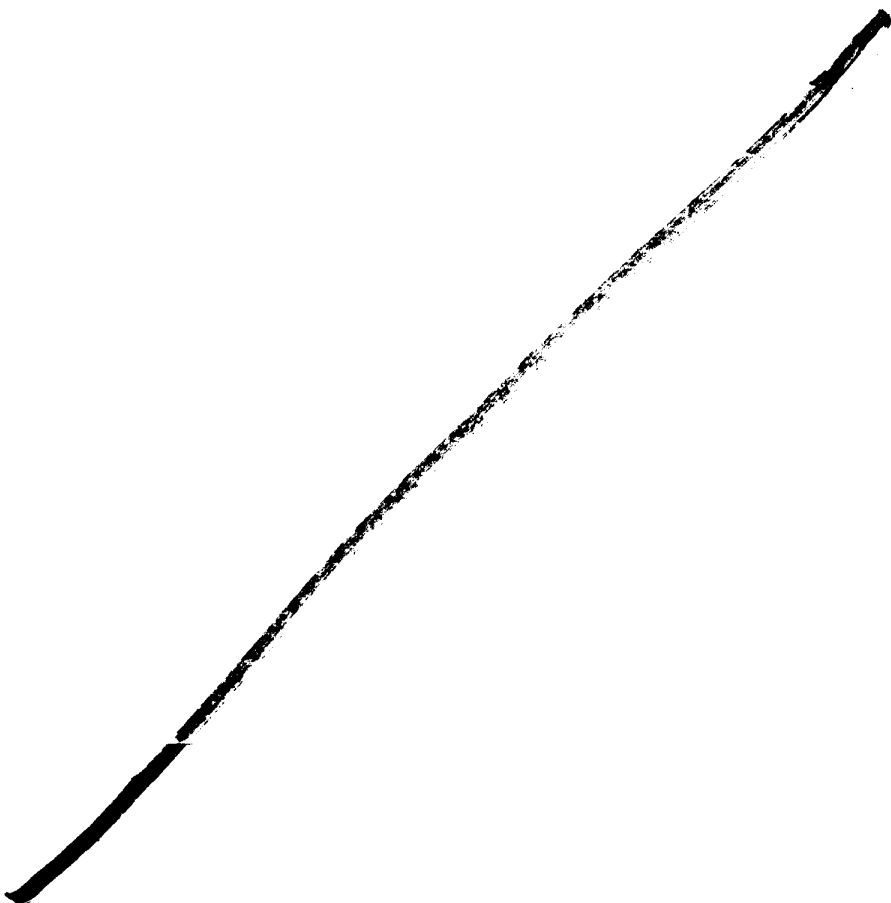
National Laboratory Certification Program

January 29, 2001

0519
Dr. Samuel E. Mathews
Baptist Medical Center-Toxicology Lab
9601 I-630, Exit 7
Little Rock, AR 72205-7299

Dear Dr. Mathews:

We have reviewed the material provided in your correspondence of January 20, 2001, submitted in response to issues raised during the sixteenth maintenance inspection of your laboratory as outlined in our correspondence of December 20, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following is a review of the material submitted:

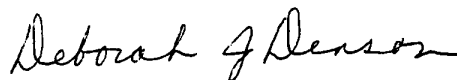


Dr. Mathews
January 29, 2001
Page 2 of 2

Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection.

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

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M16