



March 19, 1999

0514
Dr. Martin Porvaznik
Doctors Laboratory, Inc.
2906 Julia Drive
P.O. Box 2658
Valdosta, GA 31602

Dear Dr. Porvaznik:

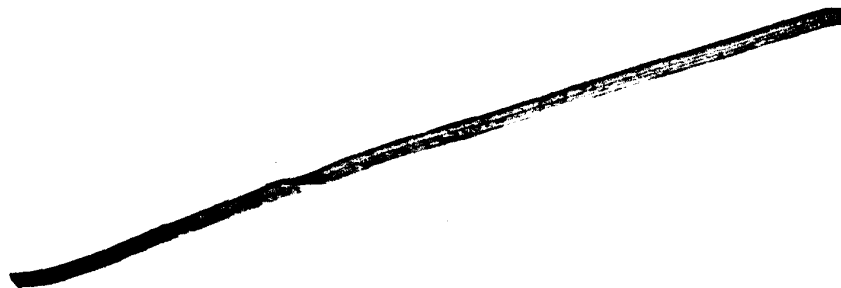
The enclosed critique was developed from the inspection reports of the inspectors who conducted the tenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. However, the following issues were raised:

E. The Standard Operating Procedures section

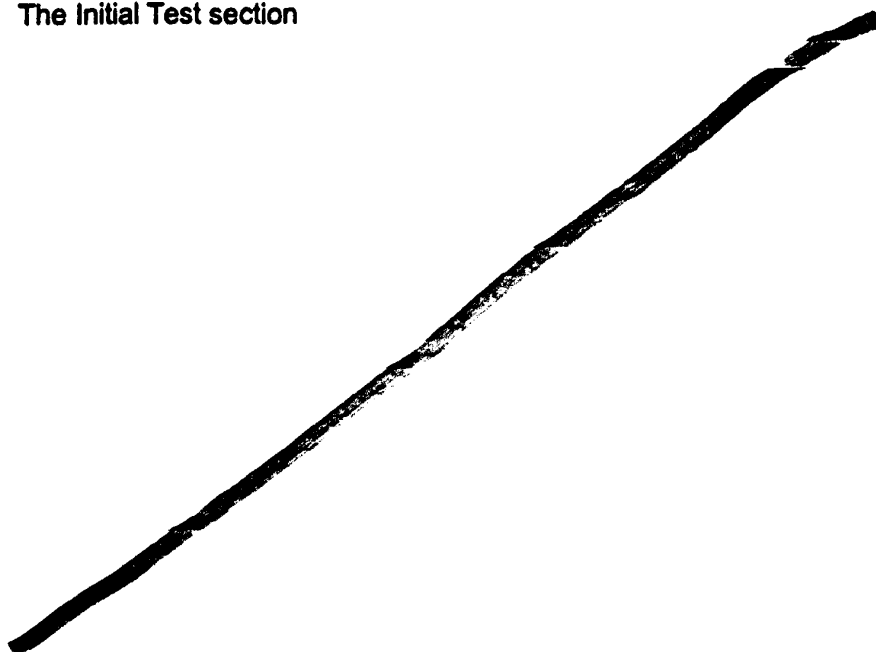
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G. The Quality Control section

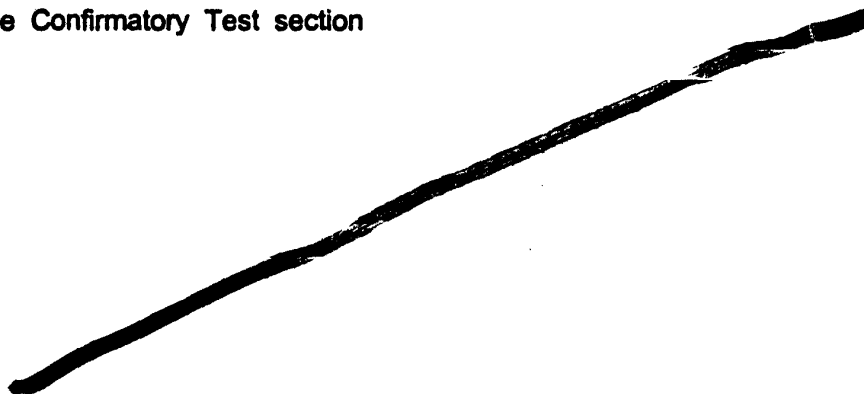
A large, thick black diagonal line redacting the content of item G.



H. The Initial Test section



I. The Confirmatory Test section



Dr. Porvaznik
March 19, 1999
Page 3 of 3

J. The Quality Control 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Inspection Analyst

Enclosure

cc: Project Files/M10



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 05
Document No. Fin

Laboratory: Doctors Laboratory, Inc.

Location: Valdosta, GA

Document Reviewed: Application Form
 Inspection Report #M10 Date: 11 February 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



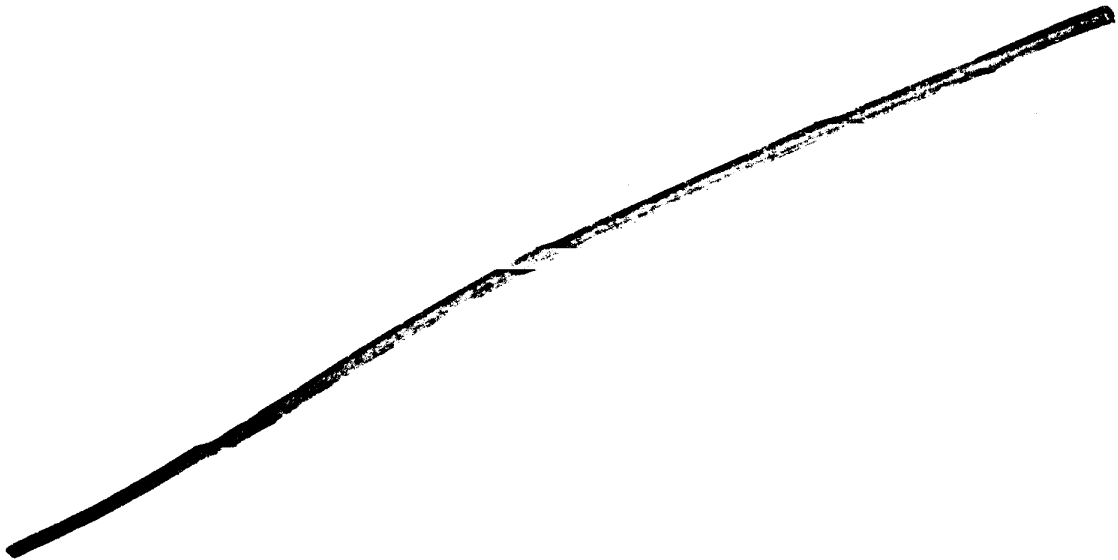
Section G. Quality Control



Section H. Initial Tests



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



DOCTORS LABORATORY, INC.

2906 Julia Drive
Valdosta, GA 31639
(912) 244-4468
(800) 342-7552
Ext. 281

received
2/16/99 DT

Martin Porvaznik, Ph.D
Director of Toxicology

Byron S. Davis, M.D.
Laboratory Director

Lamar Courson, MT(ASCP)Sc
Director of Operations

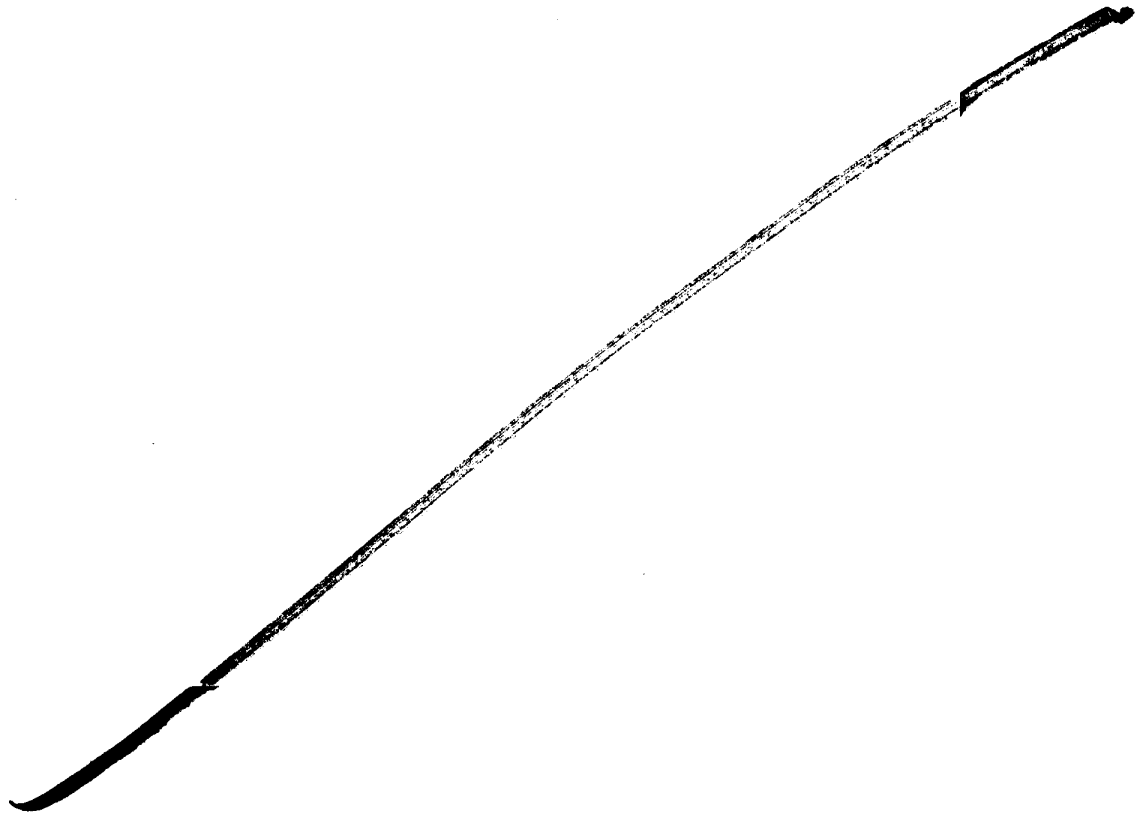
29 March 1999

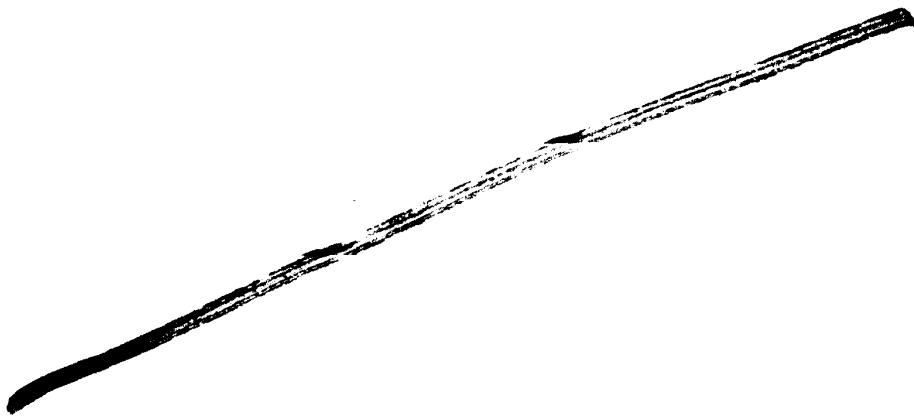
Deborah J. Denson
NLCP Inspection Analyst
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709-2194

Dear Ms Denson:

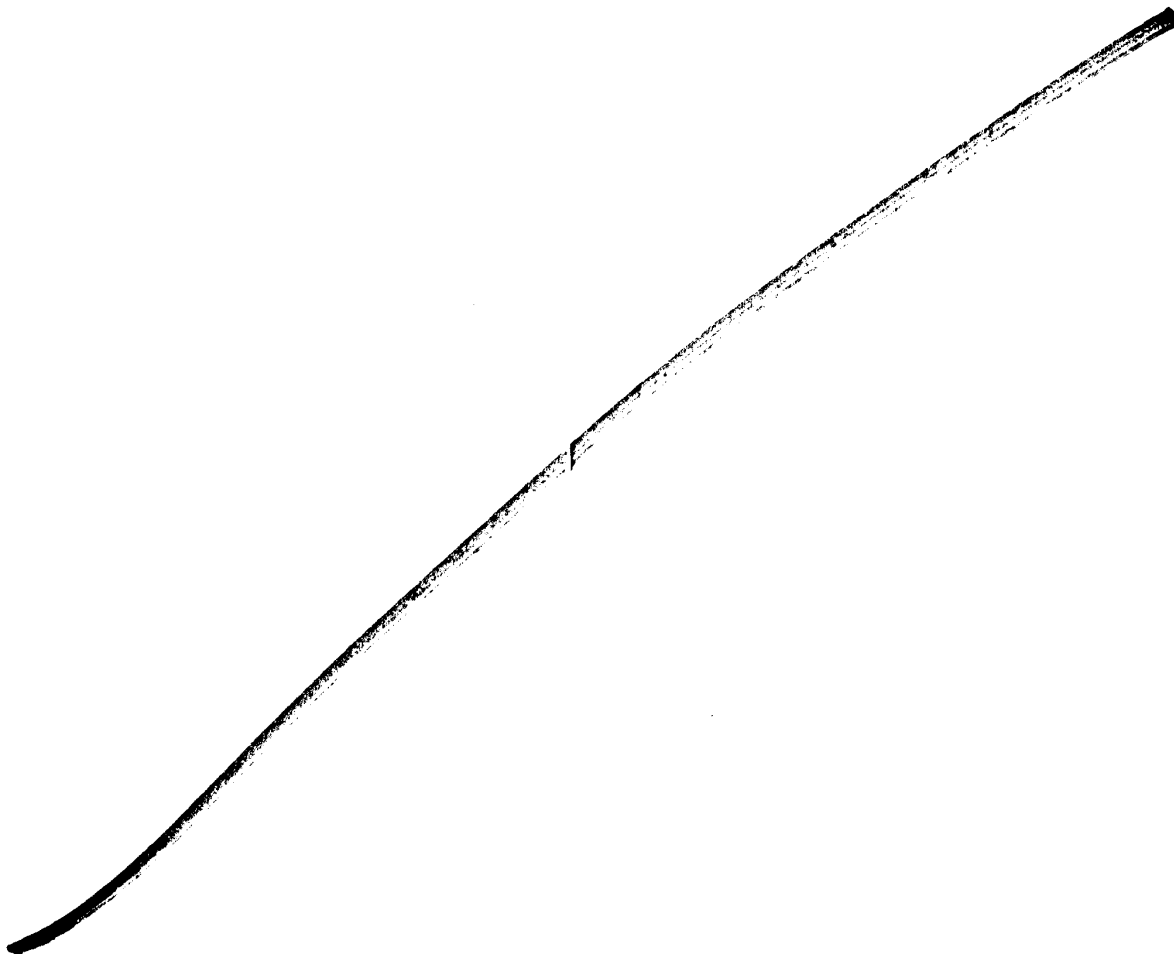
Please find enclosed my response to the critique and inspection reports of the inspectors who conducted the tenth maintenance inspection of Doctors Laboratory, Inc. (lab 0514) on 11-12 February 1999. We are pleased that the inspectors rated Doctors Laboratory, Inc. highly acceptable with the following problem areas that need to be addressed:

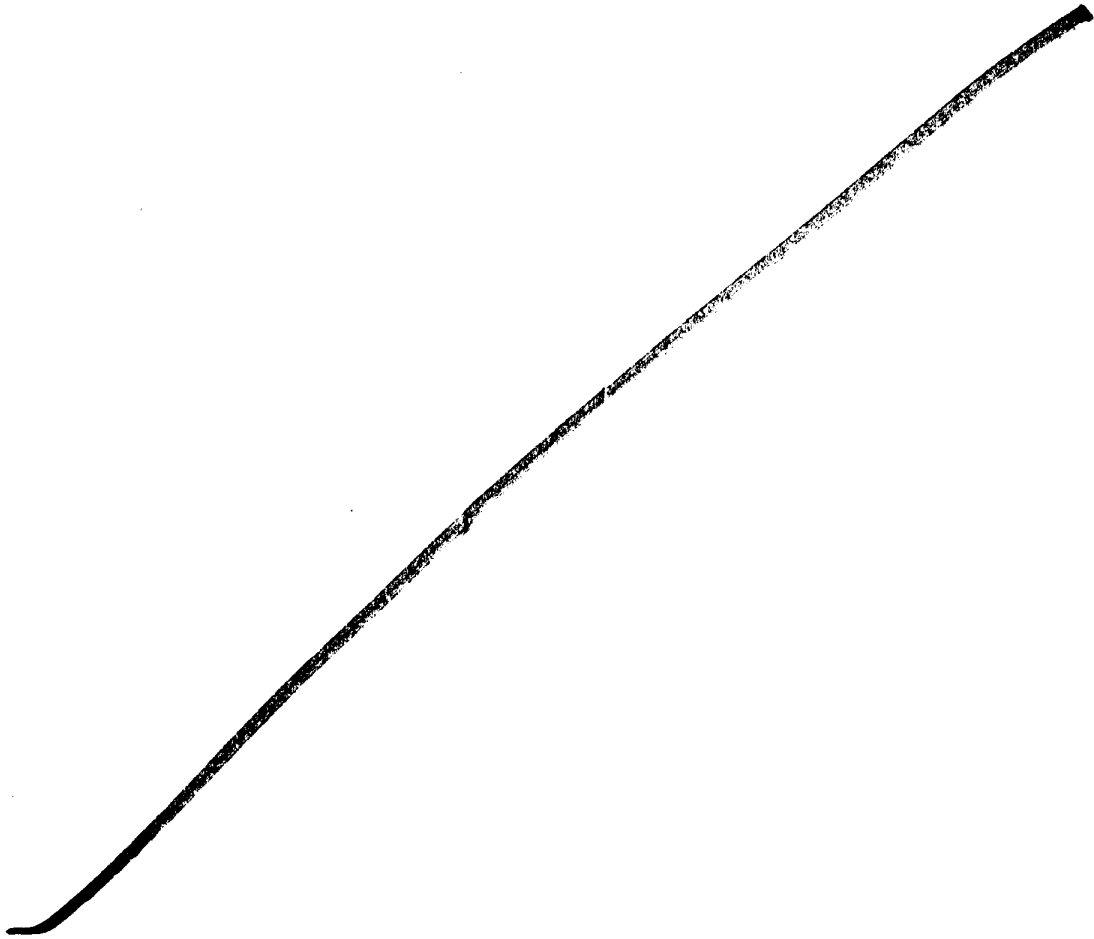
Section E. Standard Operating Procedures - Procedures Manual





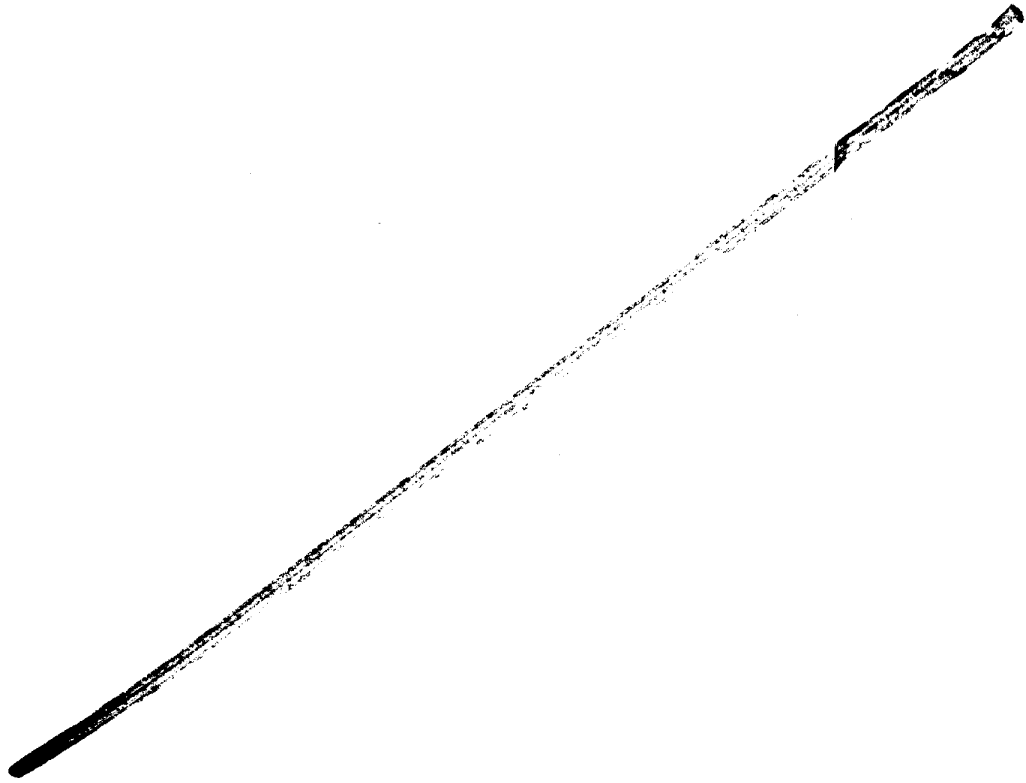
Section G. Quality Control





Section H. Initial Tests



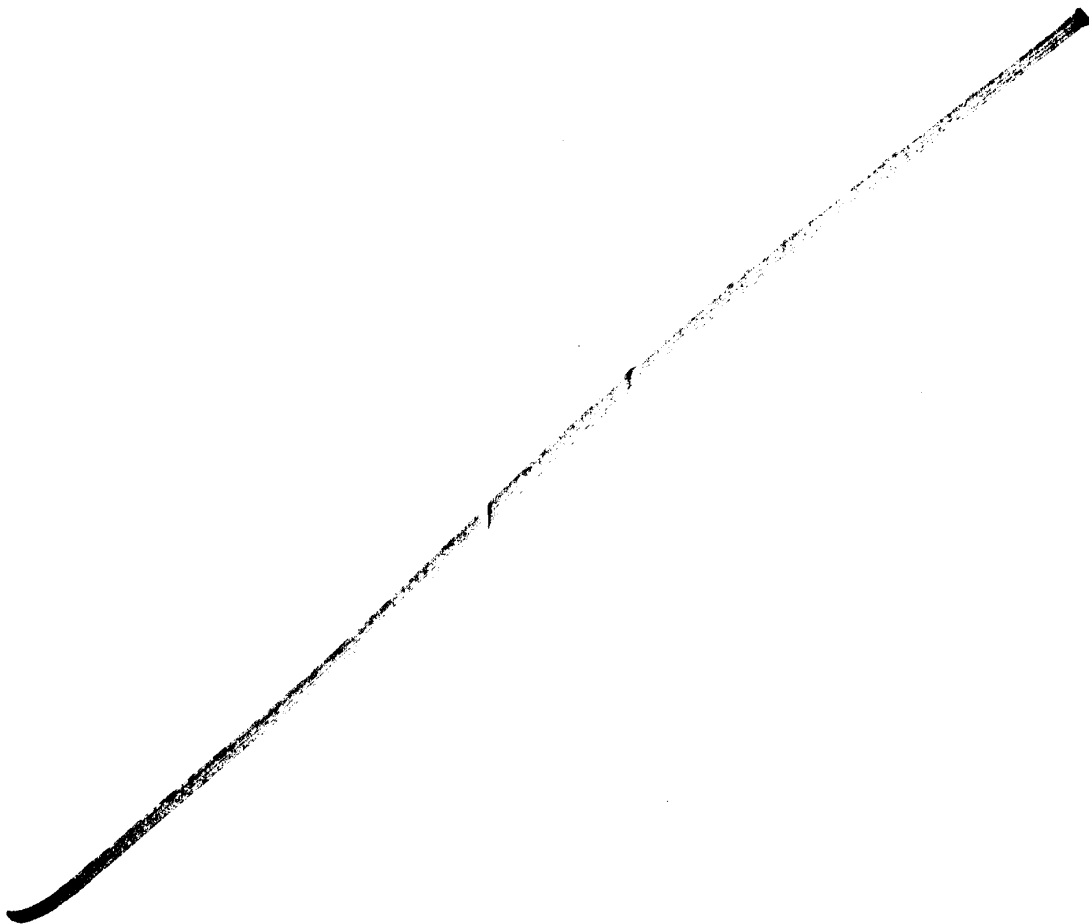


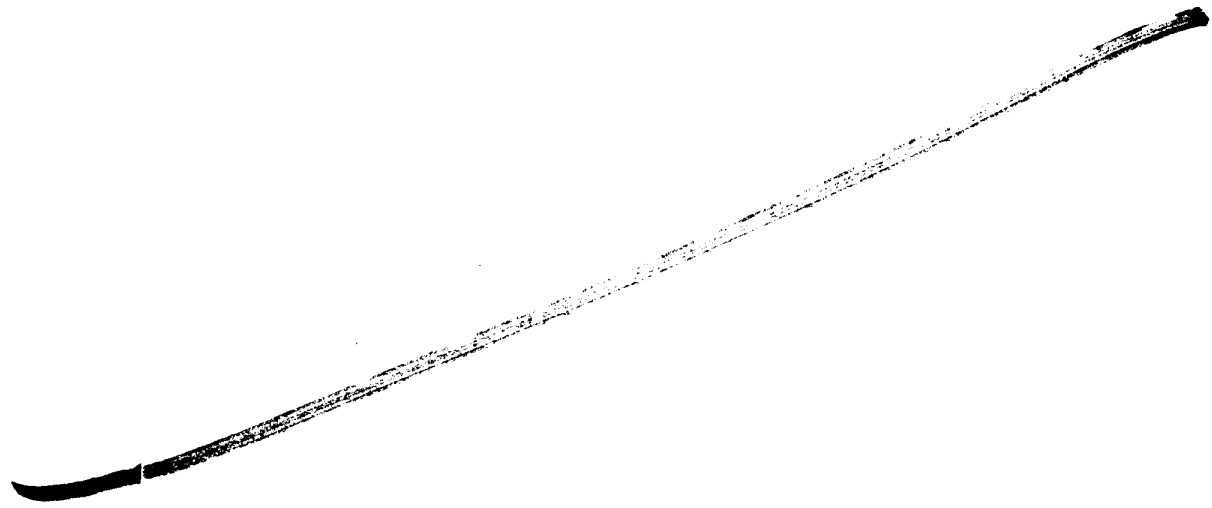
Procedure to Determine the Precision and Accuracy of the Initial Tests.



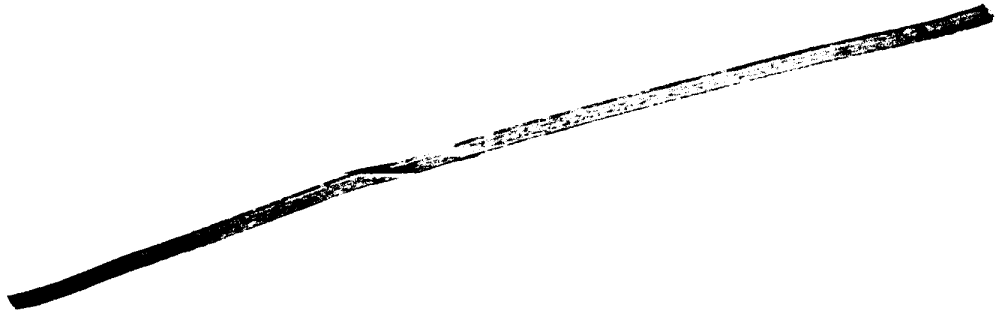


Section I. Confirmatory Tests





Section J. Records Audit



Section M. Equipment and Maintenance



Section N. Personnel

All corrective actions have been implemented as of this correspondence. I hope that this response will meet with your satisfaction for continued certification with HHS. If you have any comments that need immediate attention, please call me at (912) 244-4468, ext 281.

Sincerely,

A handwritten signature in cursive script that reads "Martin Porvaznik".

Martin Porvaznik, PhD
Director of Toxicology

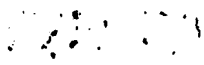
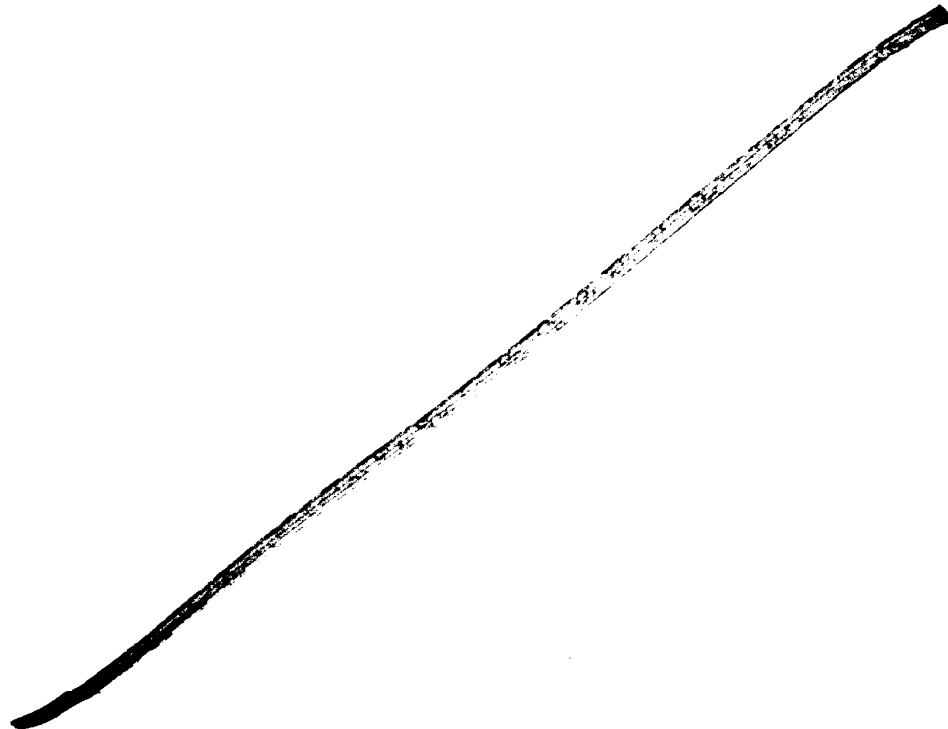


April 13, 1999

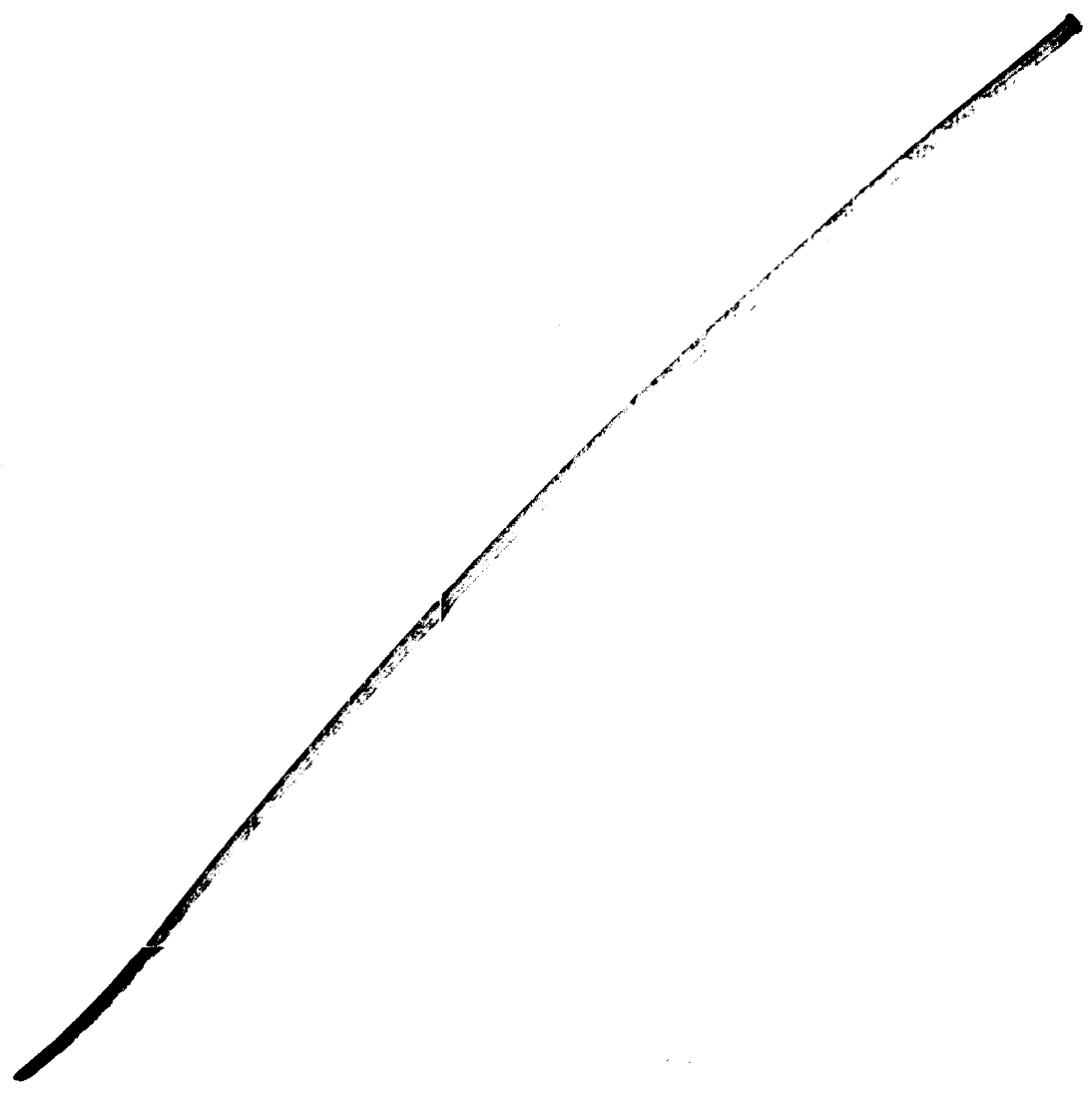
0514
Dr. Martin Porvaznik
Doctors Laboratory, Inc.
2906 Julia Drive
P.O. Box 2658
Valdosta, GA 31602

Dear Dr. Porvaznik:

We have reviewed the material provided in your correspondence of March 29, 1999, submitted in response to issues raised during the tenth maintenance inspection of your laboratory as outlined in our correspondence of March 19, 1999. 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. Porvaznik
April 13, 1999
Page 2 of 3



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.

Dr. Porvaznik
April 13, 1999
Page 3 of 3

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

Sincerely,

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

Deborah J. Denson
NLCP Inspection Analyst

cc: Project Files/M10



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

September 8, 1999

0514
Dr. Martin Porvaznik
Doctors Laboratory, Inc.
2906 Julia Drive
P.O. Box 2658
Valdosta, GA 31602

Dear Dr. Porvaznik:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the eleventh 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 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/M11



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0514
Document No. Final

Laboratory: Doctors Laboratory, Inc.

Location: Valdosta, GA

Document Reviewed: Application Form
 Inspection Report #M11 Date: 25 August 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



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 28, 2000

0514
Dr. Martin Porvaznik
Doctors Laboratory, Inc.
2906 Julia Drive
P.O. Box 2658
Valdosta, GA 31602

Dear Dr. Porvaznik:

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 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. It is *not necessary* for the laboratory to submit a written response to RTI.

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/M12



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0514
Document No. Final

Laboratory: Doctors Laboratory, Inc.

Location: Valdosta, GA

Document Reviewed: Application Form
 Inspection Report #M12 Date: 10 February 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

[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 25, 2000

0514
Dr. David C. Williams
Doctors Laboratory, Inc.
2906 Julia Drive
P.O. Box 2658
Valdosta, GA 31602

Dear Dr. Williams:

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 acceptable. Before RTI will recommend continued certification of your laboratory, the laboratory must clarify/correct the following issues raised:

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

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G. The Quality Control section

A large, thick black diagonal line redacts the text of item G.



I. The Confirmatory Tests section




J. The Records Audit section



L. The Computers, Software, and Laboratory Information Management System (LIMS) section



Dr. Williams
Page 3 of 3
10/25/00



N. The Personnel 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 Technical Analyst

Enclosure

cc: Project Files/514



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0514
Document No. Final

Laboratory: Doctors Laboratory, Inc.

Location: Valdosta, GA

Document Reviewed: Application Form
 Inspection Report #M13 Date: 10 August 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

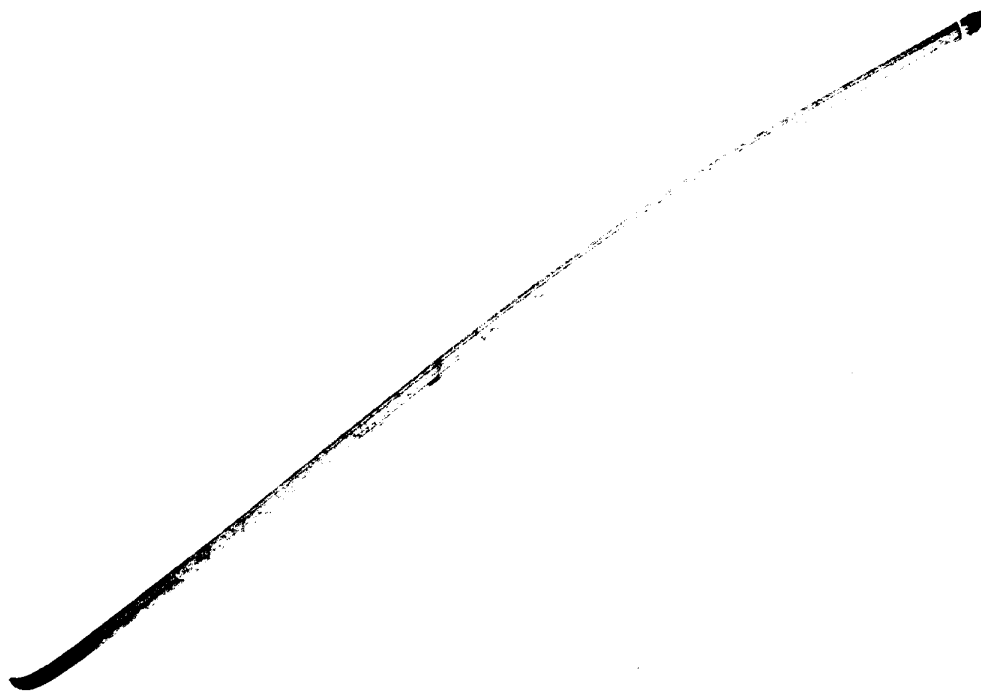





Section H. Initial Tests



Section I. Confirmatory Tests



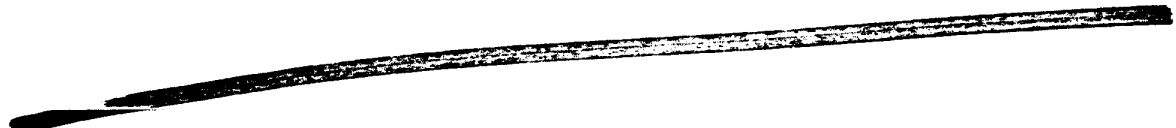
Section J. Records Audit



Section K. Reporting




Section L. Computers, Software, and LIMS

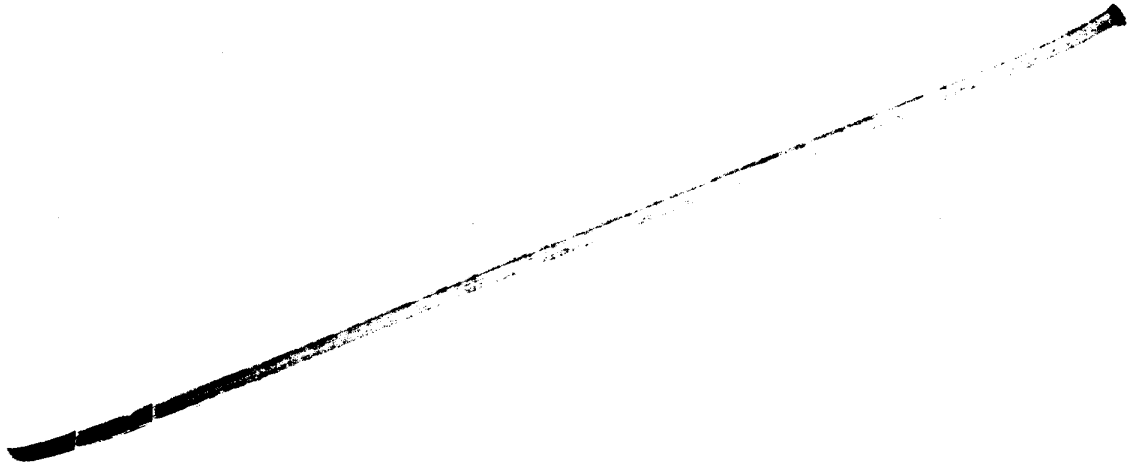


Section M. Equipment and Maintenance



Section N. Personnel





received
SDC 12/4/00

Doctors Laboratory, Inc.
P. O. Box 2658
Valdosta, GA31604

November 22, 2000

Susan Crumpton
Research Triangle Institute
P. O. Box 12194
Research Triangle Park, NC 27709-7042

Dear Ms. Crumpton,

The thorough inspection of Doctors Laboratory, Inc. aides the laboratory toward our goal of continuous process improvement. I have attempted to answer the issues raised in the August 2000 inspection (round 13), in a manner that will help improve the laboratory's performance.



I think all items addressed in the inspection report have been answered. If you feel that additional corrective action is required, we'll certainly be receptive to your suggestions.

Sincerely,



David C. Williams, Ph. D.



RESEARCH TRIANGLE INSTITUTE

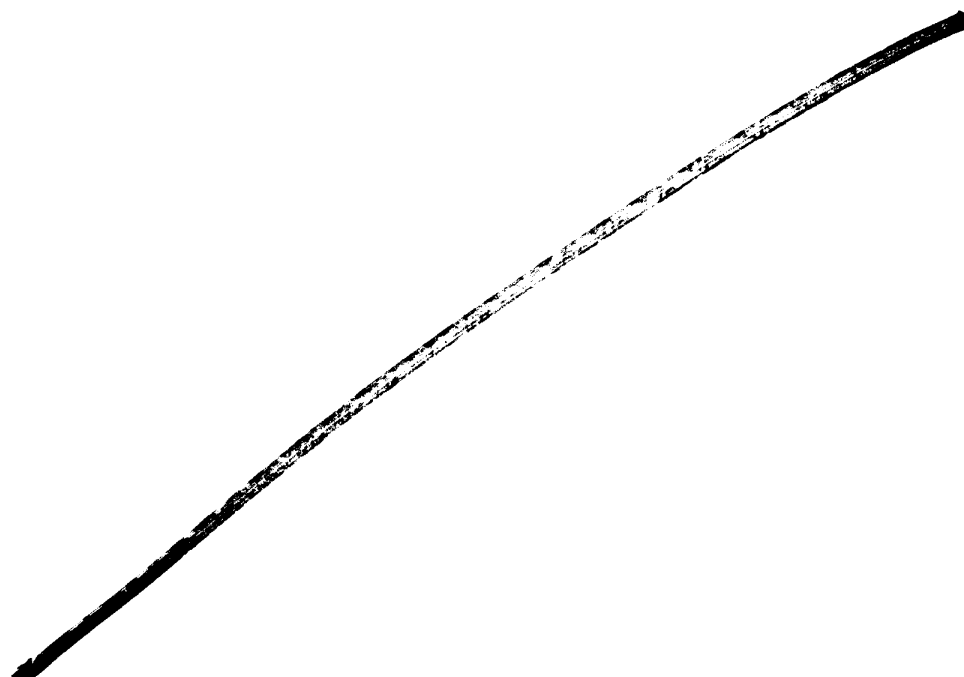
National Laboratory Certification Program

December 27, 2000


0514
Dr. David C. Williams
Doctors Laboratory, Inc.
2906 Julia Drive
P.O. Box 2658
Valdosta, GA 31602

Dear Dr. Williams:

We have reviewed the material provided in your correspondence of November 22, 2000, submitted in response to issues raised during the thirteenth maintenance inspection of your laboratory as outlined in our correspondence of October 25, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address most issues raised. However, the laboratory must take corrective action to address the following remaining issues:



Dr. Williams
Page 2 of 2
12/27/00



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.

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 Technical Analyst

cc: Dr. Michael Baylor
Project Files/0514