



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 15, 1999

0115
Mr. Prentiss Jones
South Bend Medical Foundation, Inc.
530 North Lafayette Blvd.
South Bend, IN 46601-1098

Dear Mr. Jones:

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 following issues were raised:

E. The Standard Operating Procedures (SOP) 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 Inspection Analyst



Mr. Jones
February 15, 1999
Page 2 of 2

Enclosure

cc: Project Files/M18



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0115
Document No. Final

Laboratory: South Bend Medical Foundation, Inc.

Location: South Bend, IN

Document Reviewed: Application Form
 Inspection Report #M18 Date: 21 January 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

[Redacted]



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

August 30, 1999

0115
Mr. Prentiss Jones
South Bend Medical Foundation, Inc.
530 North Lafayette Blvd.
South Bend, IN 46601-1098

Dear Mr. Jones:

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. However, the laboratory must correct/clarify the following:

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

[Redacted]


H. The Initial Tests section

[Redacted]

I. The Confirmatory Tests section

[Redacted]





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/M19



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0115
Document No. Final

Laboratory: South Bend Medical Foundation, Inc.

Location: South Bend, IN

Document Reviewed: Application Form
 Inspection Report #M19 Date: 15 July 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

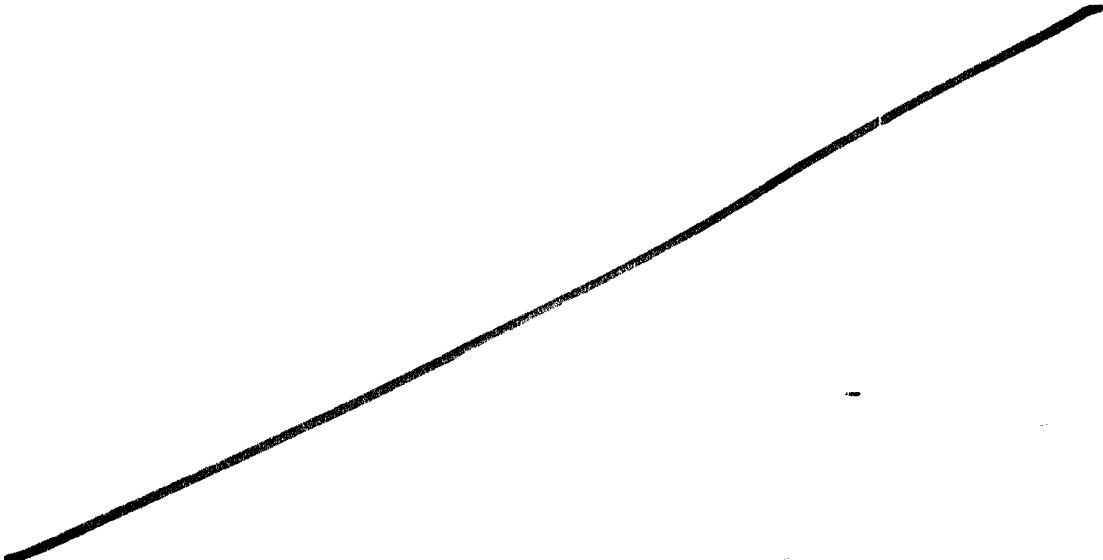
[Redacted]

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

February 16, 2000

0115
Mr. Prentiss Jones
South Bend Medical Foundation, Inc.
530 North Lafayette Blvd.
South Bend, IN 46601-1098

Dear Mr. Jones:

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

[Redacted]

G. The Quality Control section

[Redacted]

H. The Initial Tests section

[Redacted]

I. The Confirmatory Tests section

[Redacted]

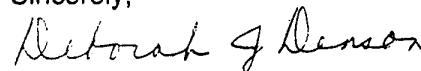


L. The Computers, Software, and LIMS section

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


Mr. Jones
February 16, 2000
Page 3 of 3

Enclosure
cc: Project Files/M20




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

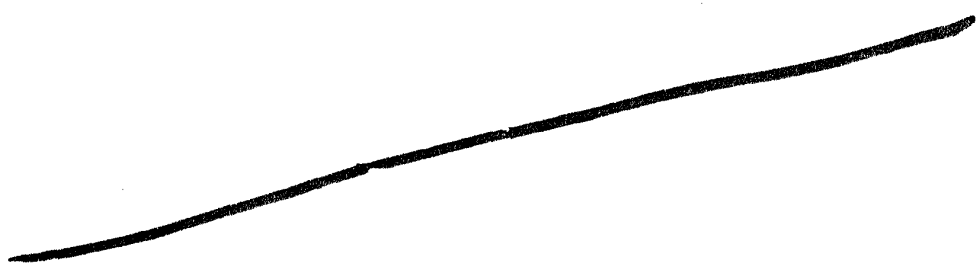
Section E. Standard Operating Procedures - Procedures Manual



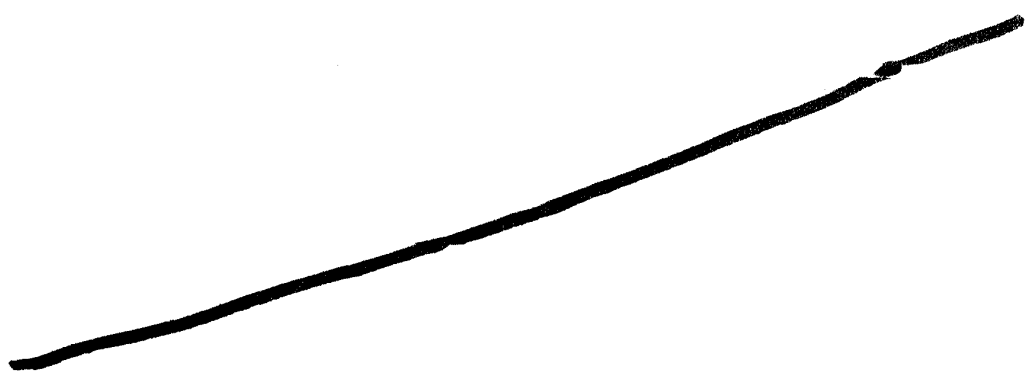
Section F. Chain-of-Custody, Accessioning, and Security



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



Section M. Equipment and Maintenance



Section N. Personnel





**SOUTH BEND
MEDICAL
FOUNDATION**

530 North Lafayette Boulevard • South Bend, IN 46601-1098
219-234-4176 • Elkhart 219-294-1519 • 800-544-0925

received
4/3/2000 DS

DEPARTMENT OF
FORENSIC TOXICOLOGY
PRENTISS JONES, JR., M.S., T.C. - NRCC
Technical Director
BETTE GAE DART
Administrative Manager
PAUL F. MOORMAN
Technical Manager

March 31, 2000
Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

In response to issues raised in the critique developed from the twentieth maintenance inspection of our laboratory, we are submitting the enclosed documents for your perusal. To facilitate your review, we have responded to the issues in the same order presented in your February 16, 2000 letter.

E. Standard Operating Procedures

[Redacted]

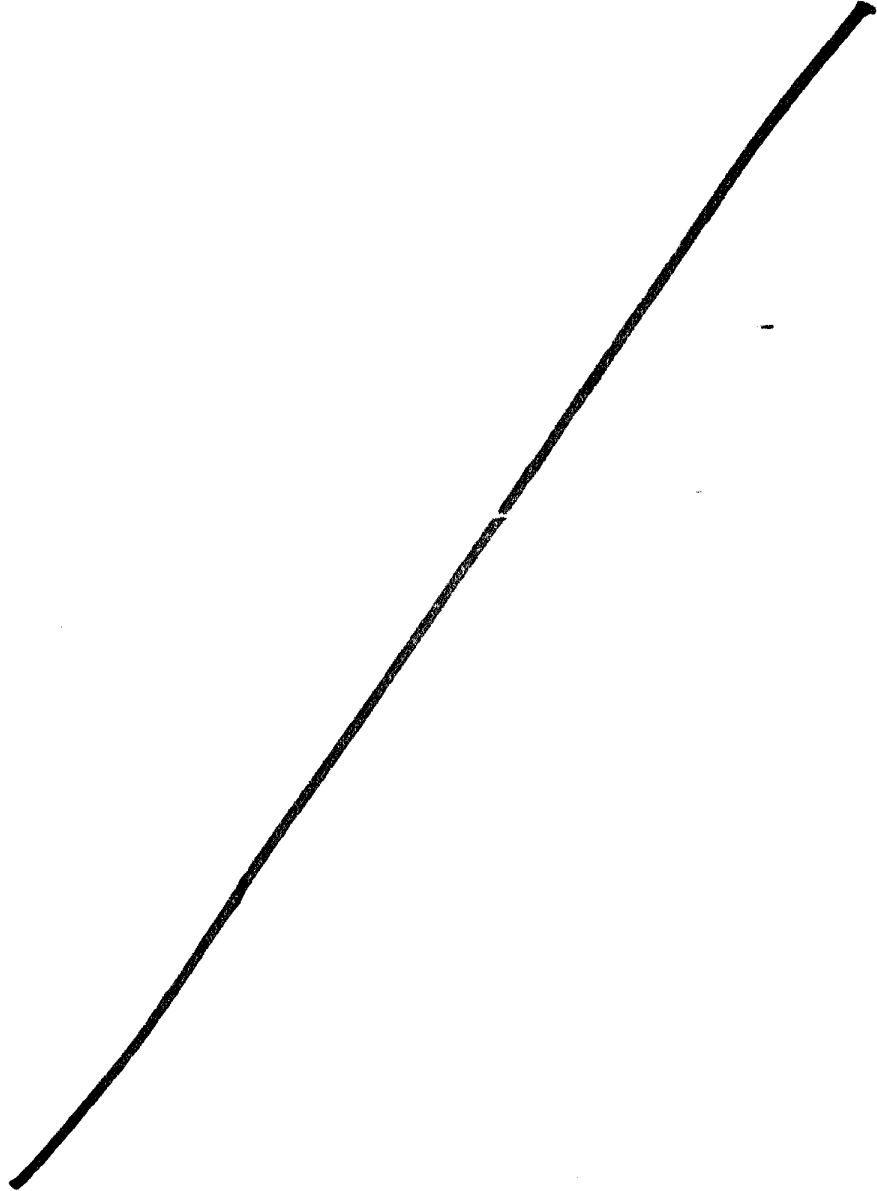
G. Quality Control

[Redacted]

H. Initial Tests

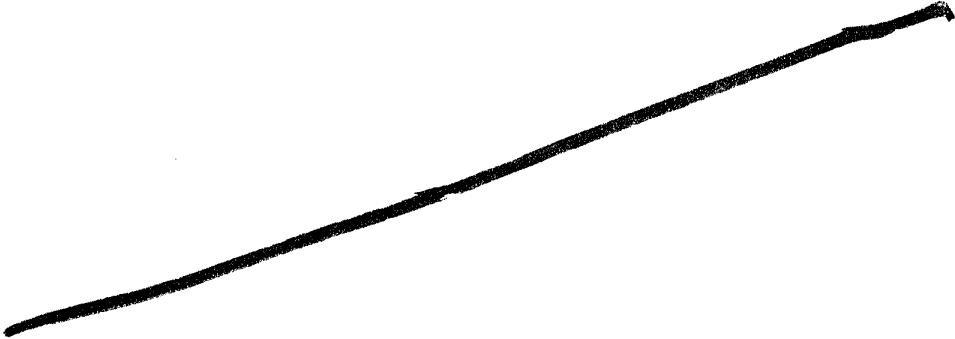
[Redacted]

I. Confirmatory Tests



L. Computers, Software, and LIMS





Lastly, we greatly appreciated the approval granted upon our request for an extension to the 30-day response period.

Please contact me with any questions you may have regarding what is herein contained.

Respectfully Submitted,



Prentiss Jones Jr. MS TC-NRCC
Technical Director Toxicology
South Bend Medical Foundation
Laboratory #0115



RESEARCH TRIANGLE INSTITUTE

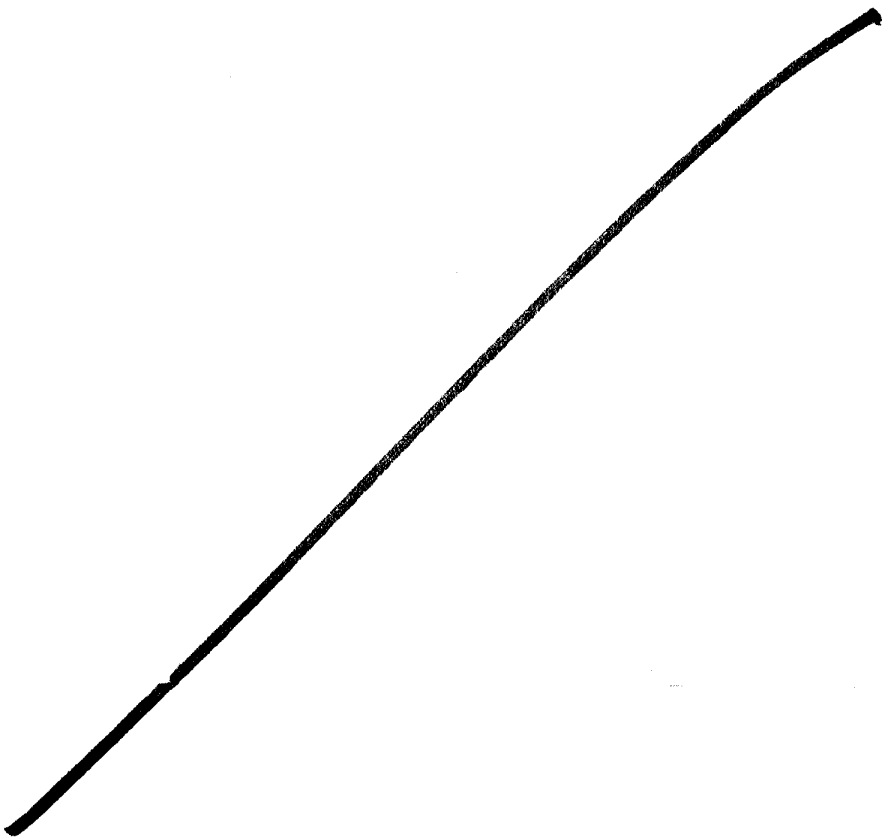
National Laboratory Certification Program

April 18, 2000

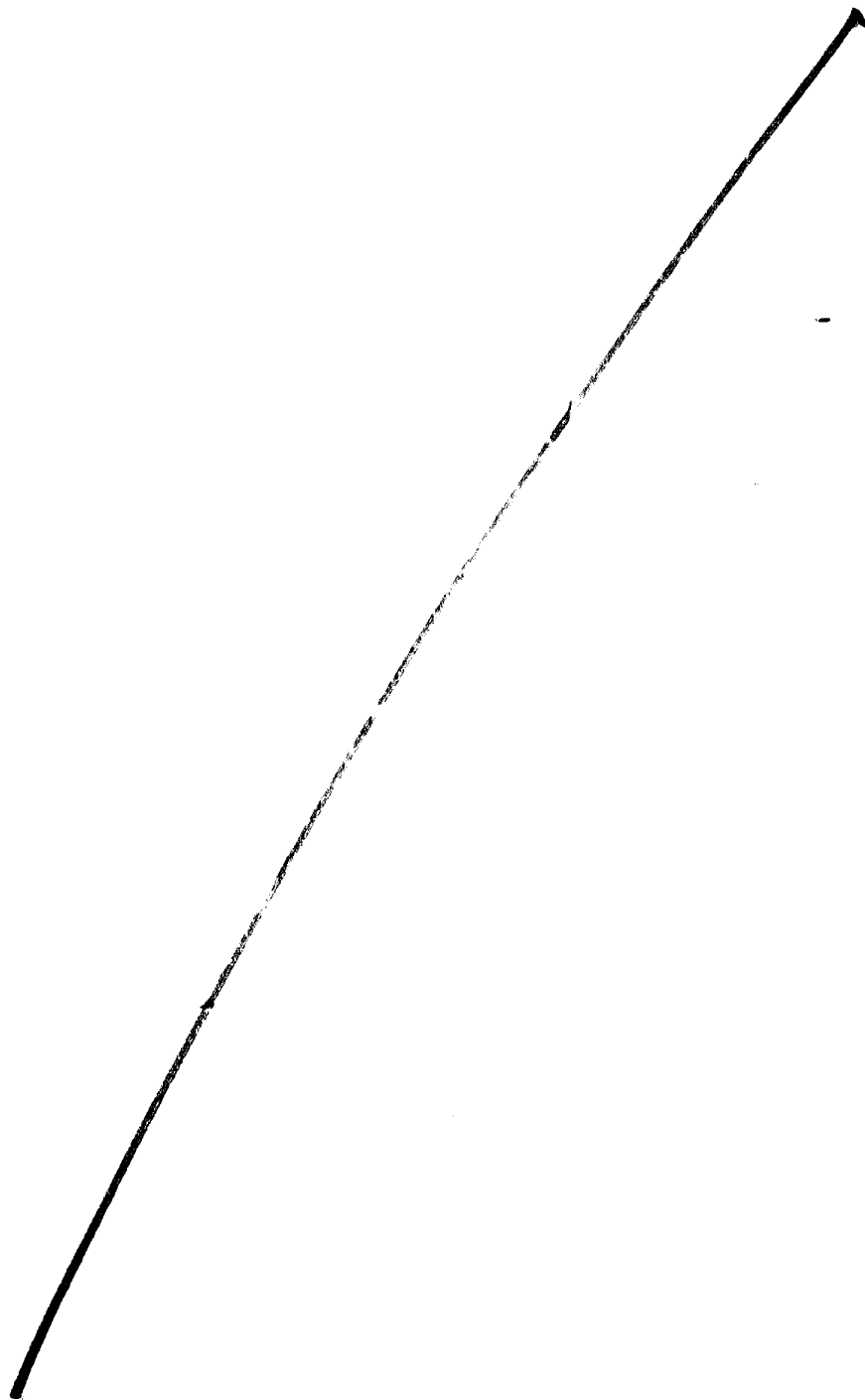
0115
Mr. Prentiss Jones
South Bend Medical Foundation, Inc.
530 North Lafayette Blvd.
South Bend, IN 46601-1098

Dear Mr. Jones:

We have reviewed the material provided in your correspondence of March 31, 2000, submitted in response to issues raised during the twentieth maintenance inspection of your laboratory as outlined in our correspondence of February 16, 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:



Mr. Jones
April 18, 2000
Page 2 of 3

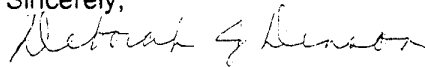


Mr. Jones
April 18, 2000
Page 3 of 3

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.

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,



Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M20

September 7, 2000

0115
Mr. Prentiss Jones
South Bend Medical Foundation, Inc.
530 North Lafayette Blvd.
South Bend, IN 46601-1098


Dear Mr. Jones:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the twenty-first 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





L. The Computers, Software, and LIMS section

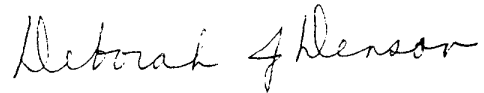


RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the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

Mr. Jones
September 7, 2000
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 Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M21



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0115
Document No. Final

Laboratory: South Bend Medical Foundation, Inc.

Location: South Bend, IN

Document Reviewed: Application Form
 Inspection Report #M21 Date: 13 July 2000
 Other _____

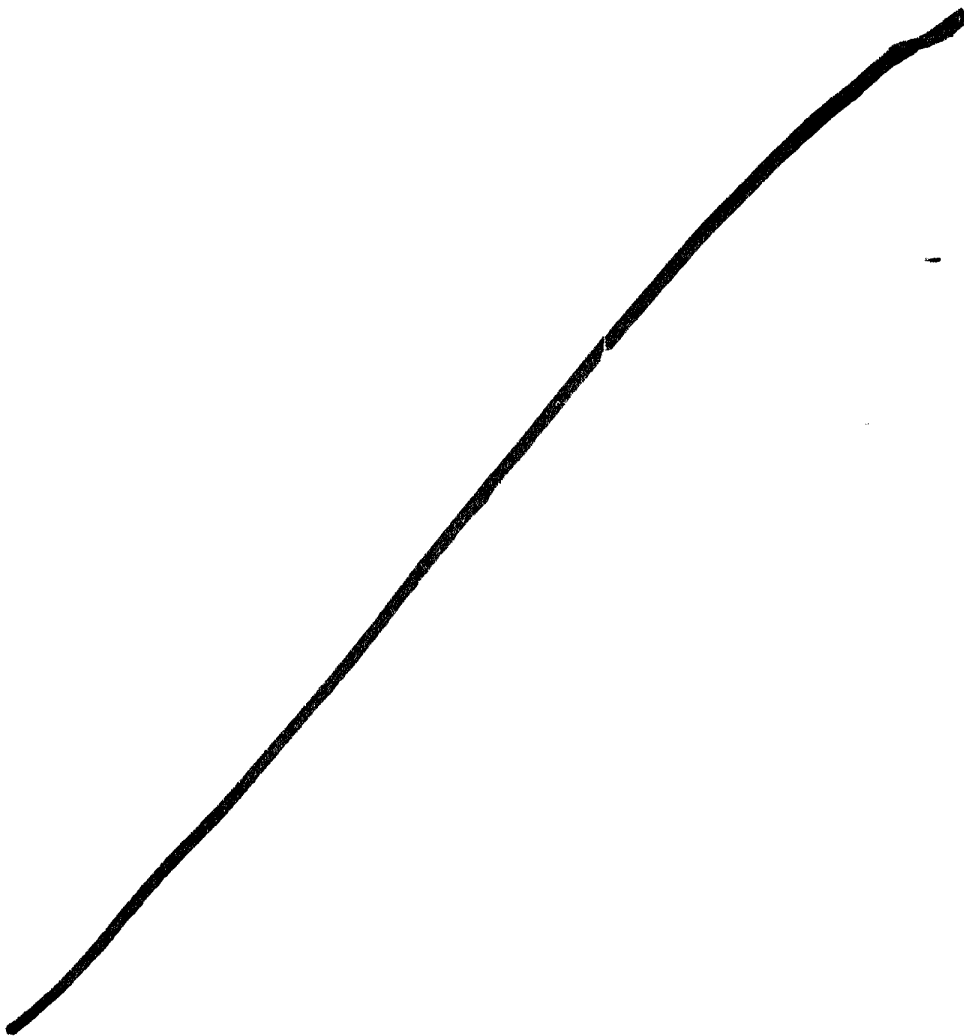
Status: Highly Acceptable Acceptable
 Unacceptable Failure

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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

[REDACTED]