Validity Testing Information Part I

Laboratory Name: SOUTHBEND MEDICAL FOUNDATION
Address: 530 N Lafayette Blvd, SOUTH BEND IN 46601

Responsible Person: Prentiss Jones Jr (Printed Name)

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Signature, Responsible Person

OCTOBER 5, 2000
Date

Prentiss Jones Jr
Printed Name, Responsible Person

Validity Testing Information Part II

Conduct an audit of all DOT regulated specimens from the date your laboratory started validity testing. Summarize your findings in an Excel spread sheet in both hard copy and electronic format. Provide the following information in a separate column of the spreadsheet/audit for *each* DOT regulated specimen that was reported either adulterated or substituted:

- **Specimen ID number**
- **Laboratory Accession Number**
- **Date of receipt**
- **Date reported**
- **Reported result (i.e., adulterated or substituted)**
- **Quantitative test result (e.g., actual creatinine concentration and specific gravity reading; actual pH reading; adulterant identity and its concentration if applicable)**

Note: Retain a copy of this information to ensure that you would be able to retrieve additional data.

I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Signature, Responsible Person

Oct 5 2000
Date

Printed Name, Responsible Person

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Signature, Responsible Person

Oct 18 2000
Date

PRENTISS JONES
Printed Name, Responsible Person

South Bend Medical Foundation / NLCP Laboratory #0115

Spec #.	Lab Access #	Received	Reported	Result	Creat	Sp. Gr.	pH	Adulterant	Adult. Quant

South Bend Medical Foundation / NLCP Laboratory #0115

Spec #.	Lab Access #	Received	Reported	Result	Creat	Sp. Gr.	pH	Adulterant	Adult. Quant

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 15, 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 report associated with the October 25-27, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to address the following issues raised:

K11. The following issues were raised during records review:

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

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. 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/svt115

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

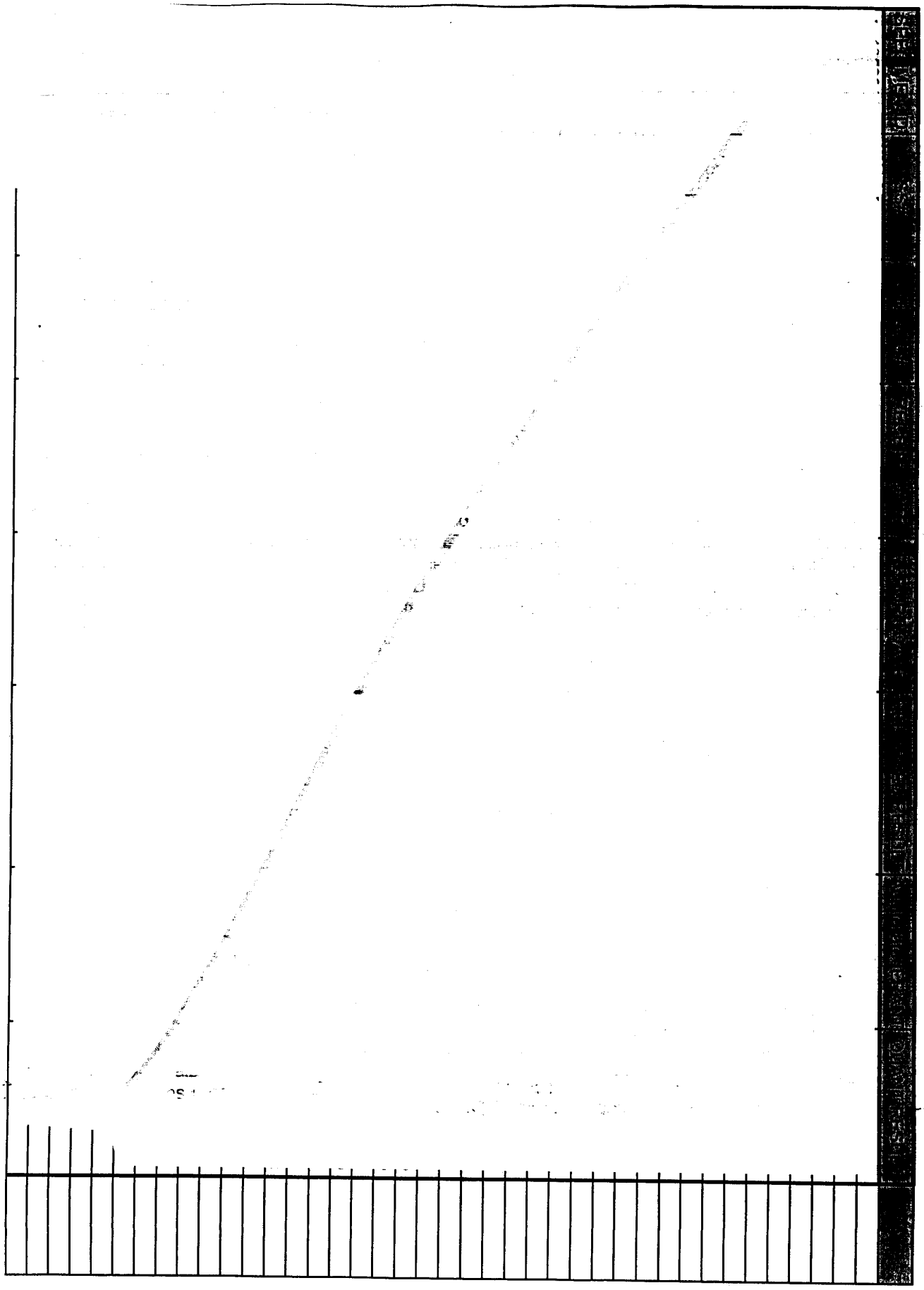
Laboratory: South Bend Medical Foundation, Inc.

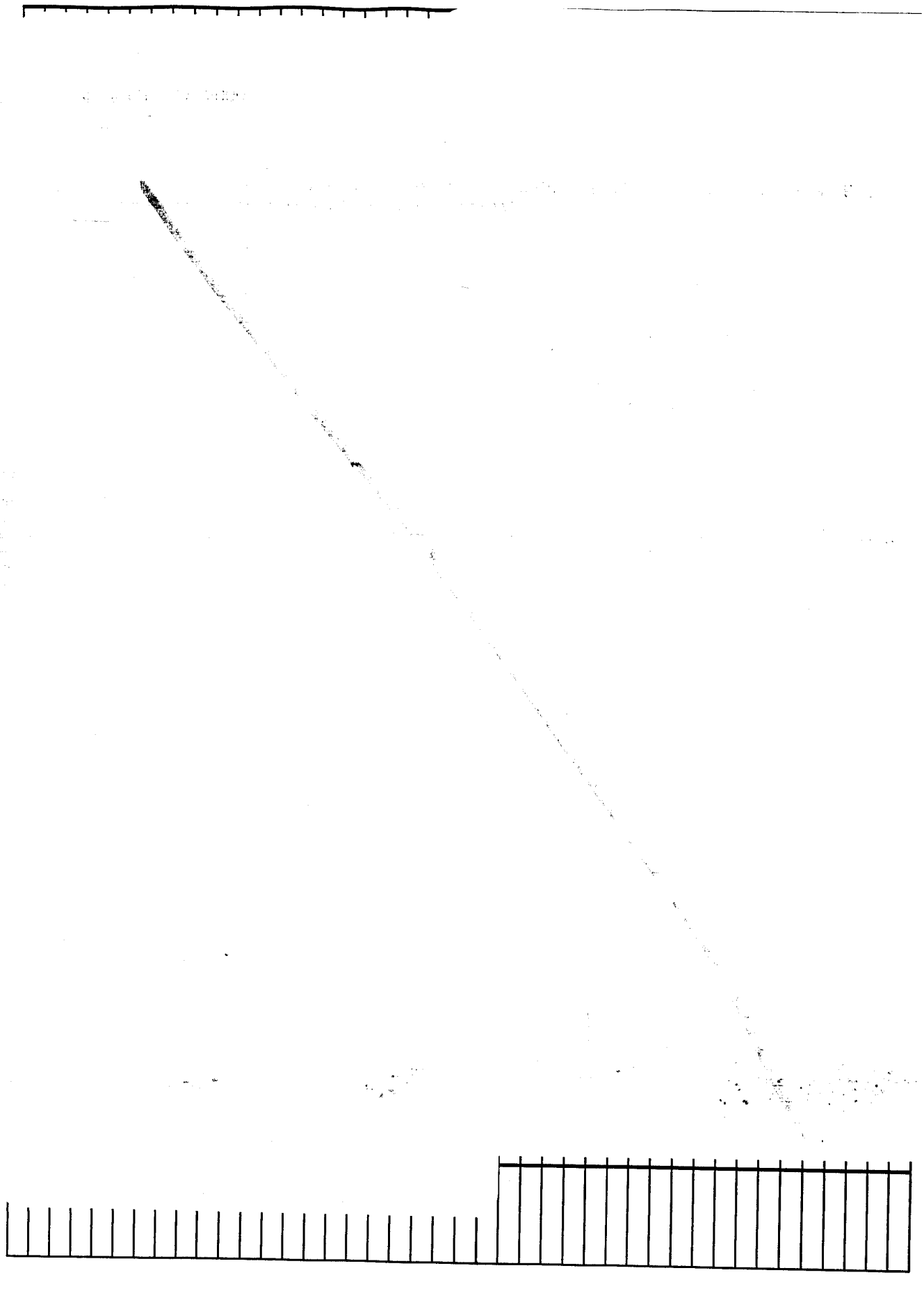
Location: South Bend, IN

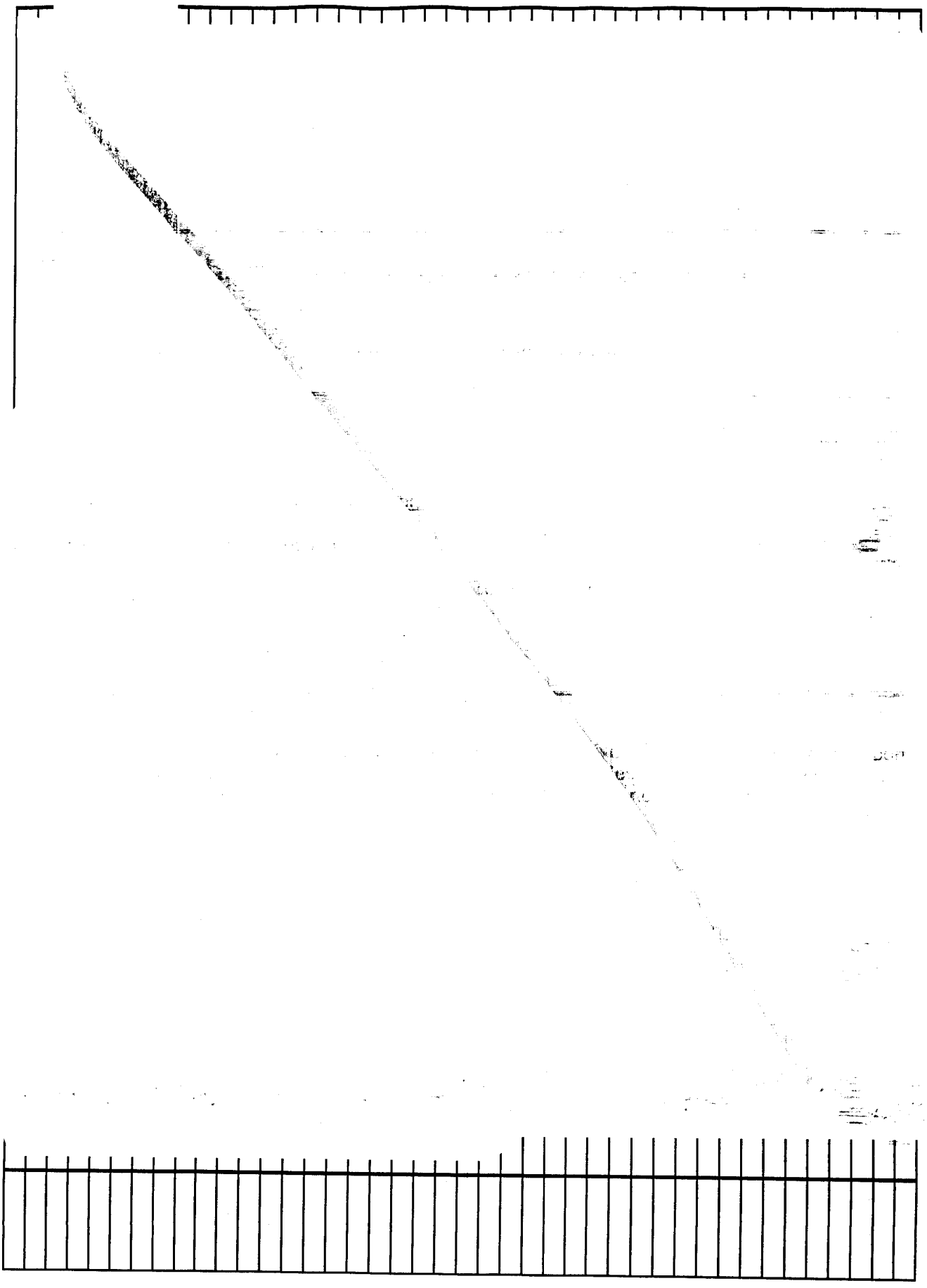
Document Reviewed: [XX] Specimen Validity Testing Inspection Report

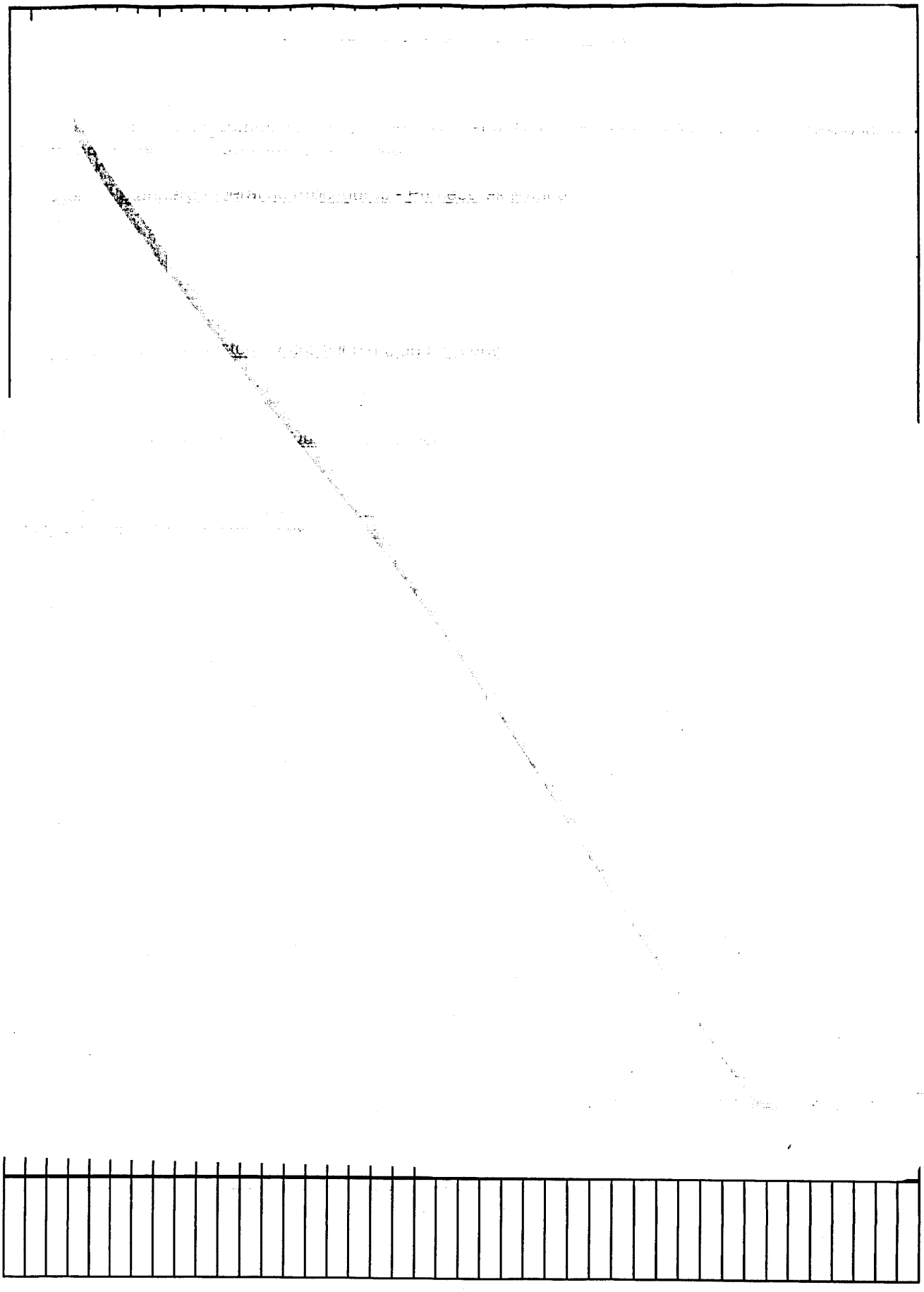
Date: 25 October 2000

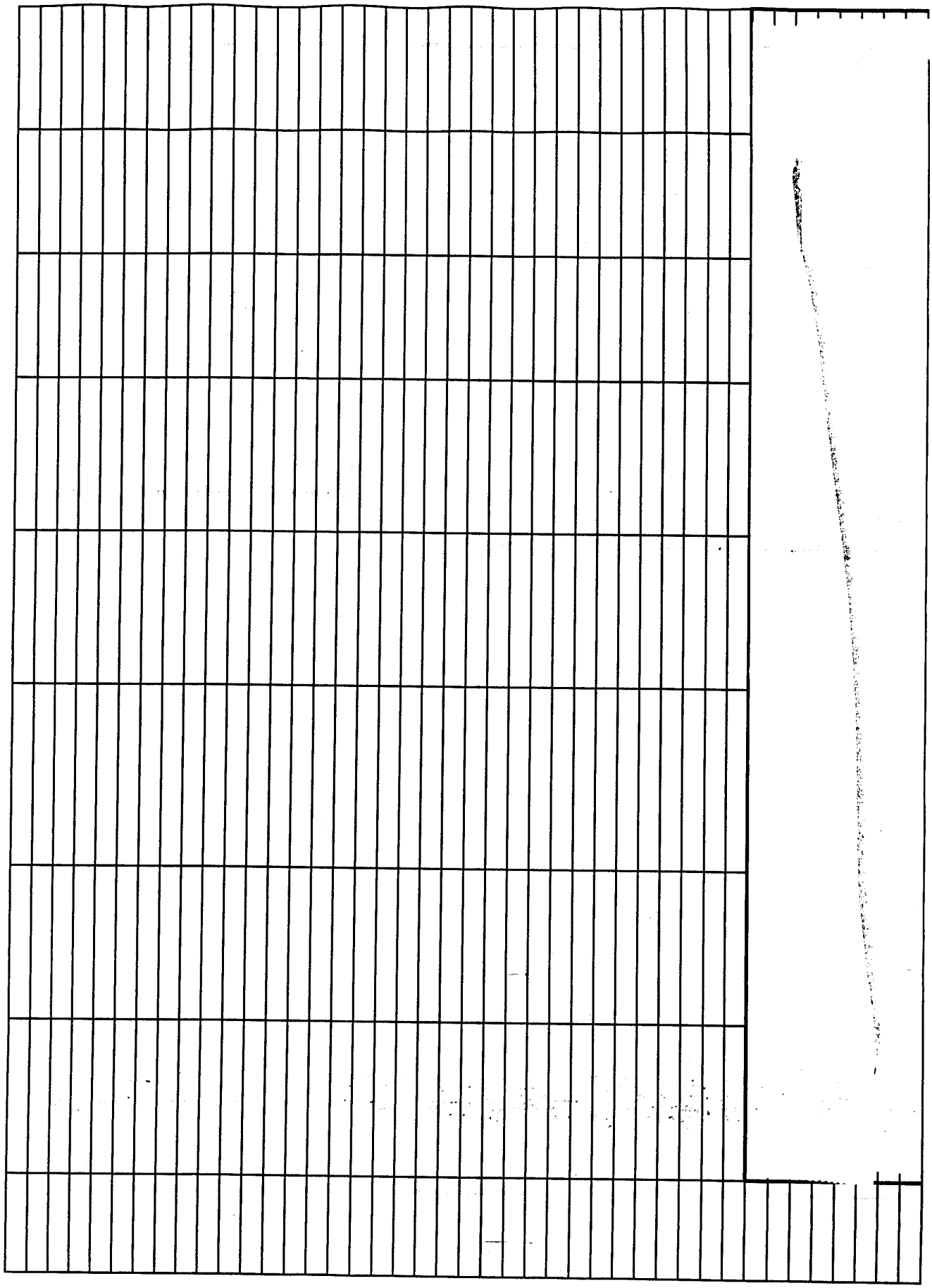
A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.











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 I. Specimen Validity Tests

Section K. Records Audit

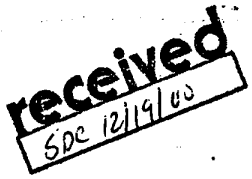
Section L. Certification and Reporting

SOUTH BEND
MEDICAL
FOUNDATION

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

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

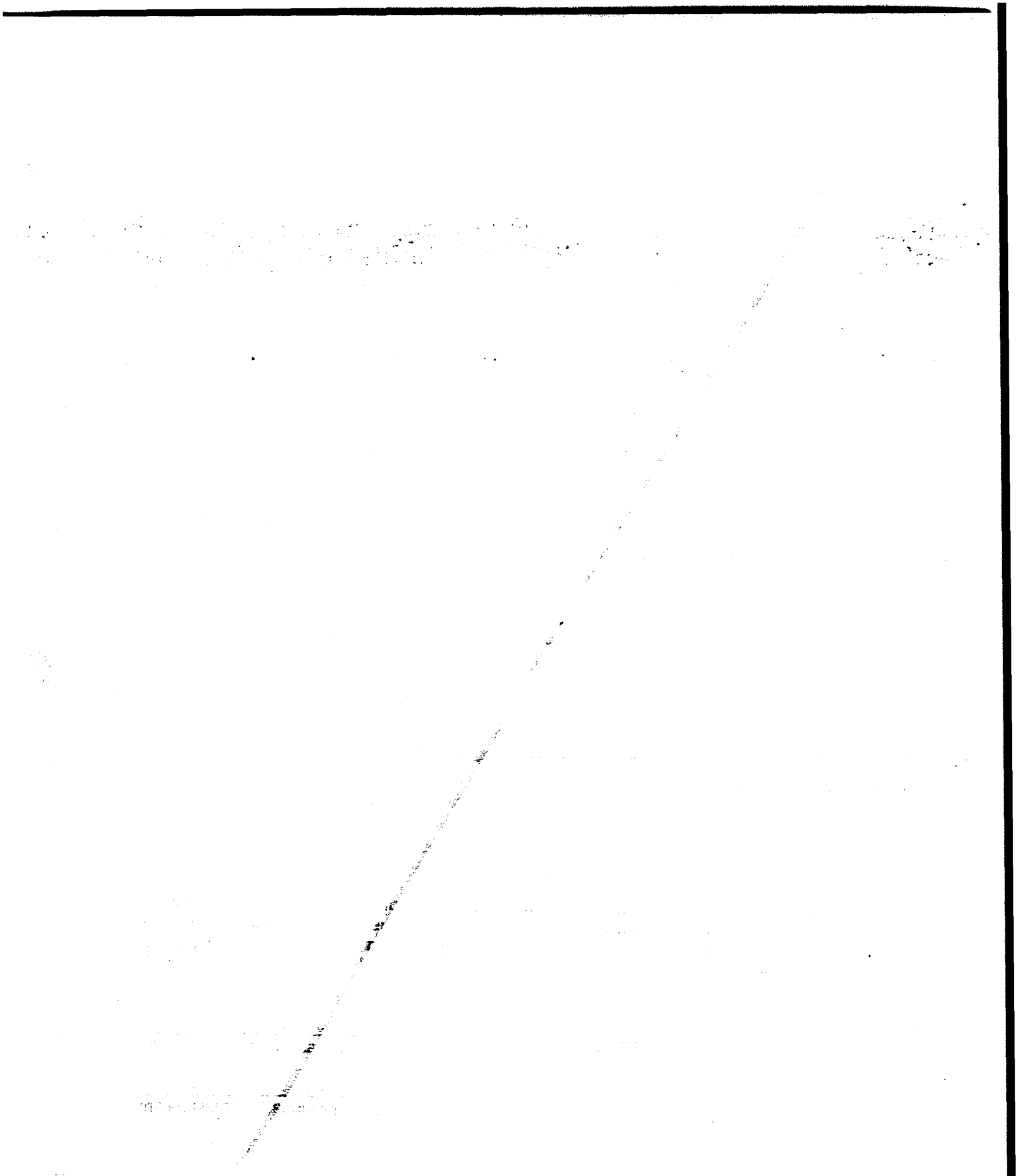
December 11, 2000
Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194



Dear Ms. Crumpton:

In response to issues raised in the critique developed from the October 25-27, 2000, specimen validity testing inspection of our laboratory, we are submitting the enclosed documents. To facilitate your review, we have organized our response to these issues in accordance with your letter of November 15, 2000.

The data audit identified the following issues:



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

December 20, 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 December 11, 2000, submitted in response to issues raised during the October 25-27, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 15, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. However, the following issue requires additional clarification and corrective action:

All corrective actions must be implemented within 30 days of the receipt of this correspondence. ***Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.*** All corrective actions 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0115

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Telephone 919 541-6709 • Fax 919 541-7042

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 10, 2001

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 January 8, 2001, submitted in response to our correspondence of December 20, 2000. The laboratory submitted information from the Medical Review Officer (MRO) on the final disposition of specimen FT99-106918.

Based upon our review of the material submitted following the laboratory's October 25-27, 2000, specimen validity testing inspection, it appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. All corrective actions will be reviewed during the next inspection. Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.

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

Sincerely,

Susan Crumpton
NLCP Technical Analyst

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