Validity Testing Information Part I

Laboratory Name: S.E.D. Medical Laboratories
Address: 5601 Office Blvd NE ABQ NM 87109

Responsible Person: Martin J. Brady (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).

Martin J. Brady
Signature, Responsible Person

10/5/00
Date

Martin J. Brady
Printed Name, Responsible Person

S.E.D. MEDICAL LABORATORIES

Toxicology

5601 OFFICE BLVD NE; ALBUQUERQUE, NM 87109

TO: Kenneth H. Davis, Jr.

COMPANY: RTI FAX # 919-541-7042

FROM: MARTIN BRADY

DEPARTMENT: TOXICOLOGY

PHONE: (505) 727-6334 FAX#: (505) 727-6327
(800) 999-5227 X 6334

Number of Pages (Include Cover): 3 Date Sent: 10/5/00

NOTES:
Original to follow.
Validity Testing Information Part I

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).

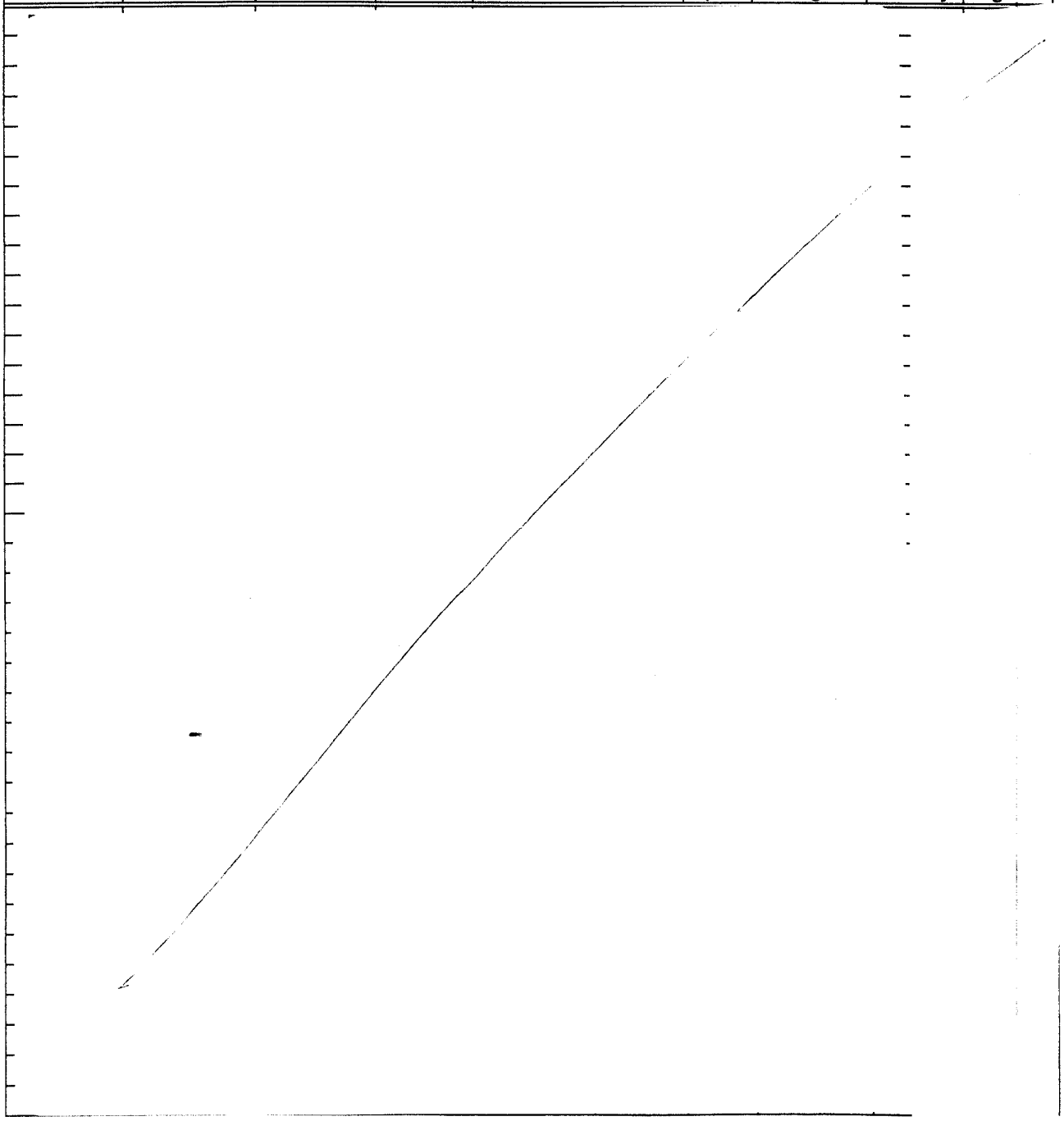
Martin J. Brady
Signature, Responsible Person

10/16/00
Date

Martin J. Brady
Printed Name, Responsible Person

S.E.D. Medical Laboratories
Validity Testing Information Part II

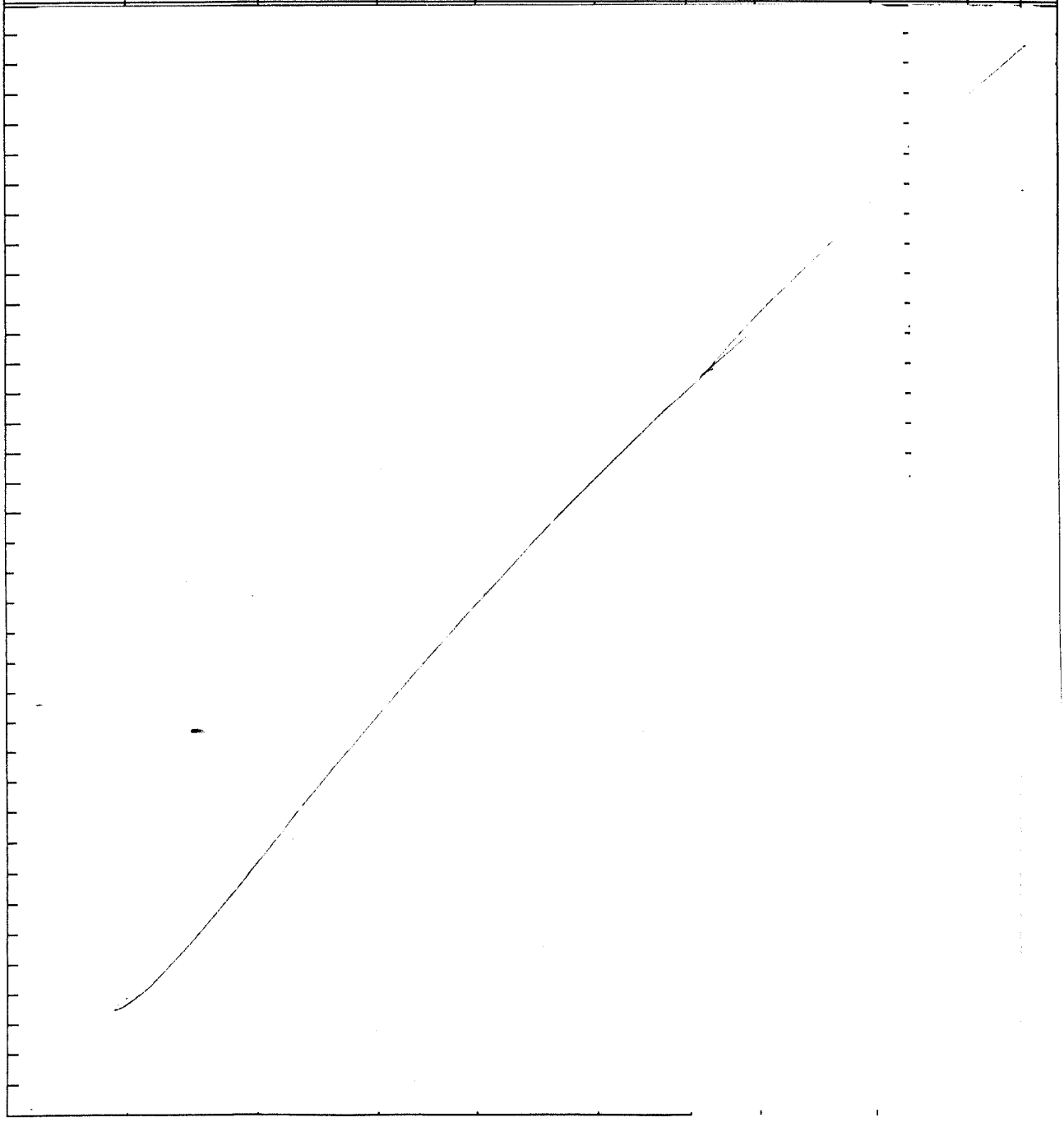
REQUISITION NUMBER	ACCESSION NUMBER	DATE RECEIVED	DATE REPORTED	REPORTED AS	QUANTITATIVE TEST RESULT			
					pH	Creatinine in mg/dL	Specific Gravity	Nitrites in ug/mL



10/16/00

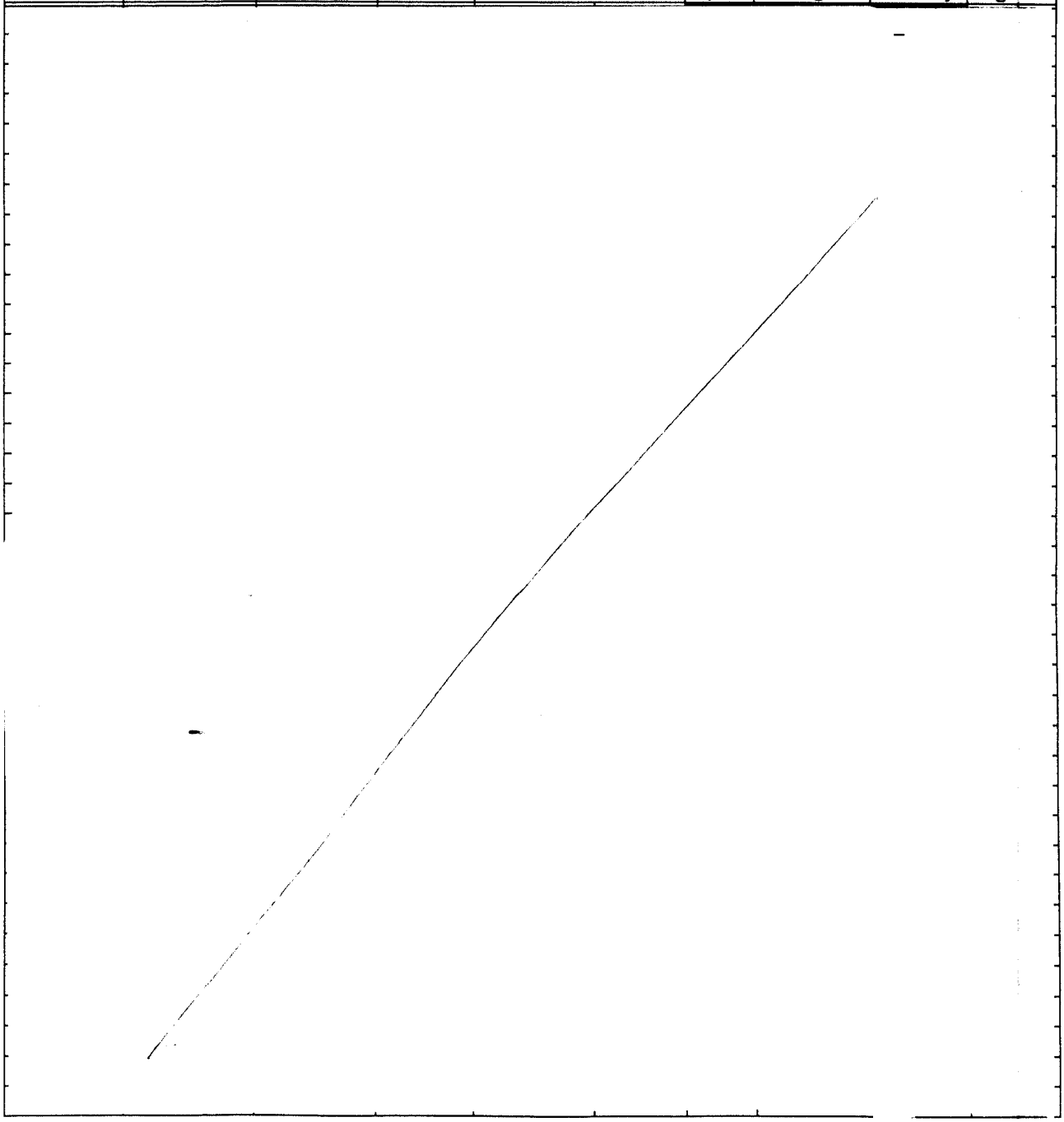
S.E.D. Medical Laboratories
Validity Testing Information Part II

REQUISITION NUMBER	ACCESSION NUMBER	DATE RECEIVED	DATE REPORTED	REPORTED AS	QUANTITATIVE TEST RESULT			
					pH	Creatinine in mg/dL	Specific Gravity	Nitrites in ug/mL



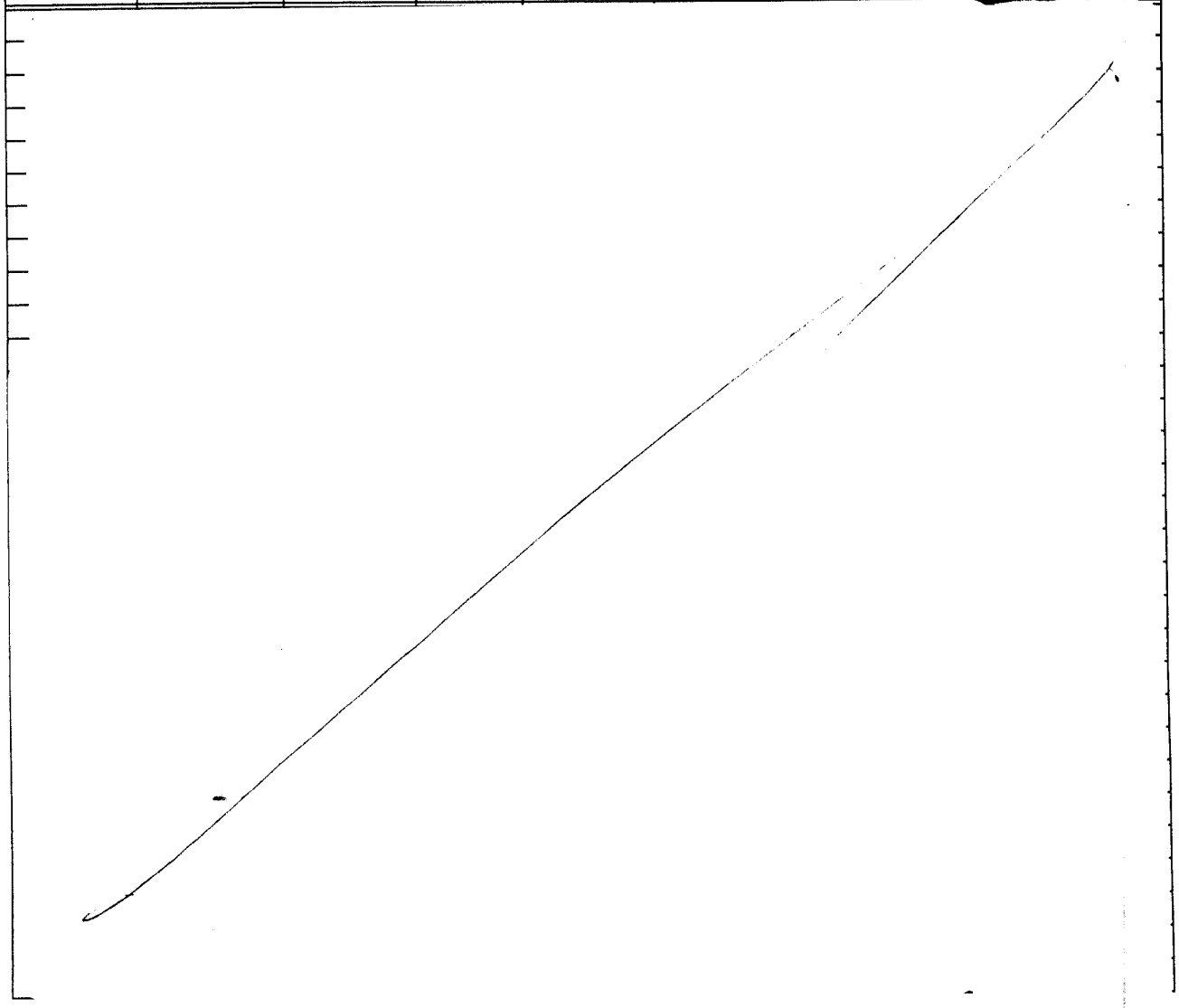
S.E.D. Medical Laboratories
Validity Testing Information Part II

REQUISITION NUMBER	ACCESSION NUMBER	DATE RECEIVED	DATE REPORTED	REPORTED AS	QUANTITATIVE TEST RESULT			
					pH	Creatinine in mg/dL	Specific Gravity	Nitrites in ug/mL



S.E.D. Medical Laboratories
Validity Testing Information Part II

REQUISITION NUMBER	ACCESSION NUMBER	DATE RECEIVED	DATE REPORTED	REPORTED AS	QUANTITATIVE TEST RESULT			
					pH	Creatinine in mg/dL	Specific Gravity	Nitrites in ug/mL



RESEARCH TRIANGLE INSTITUTE

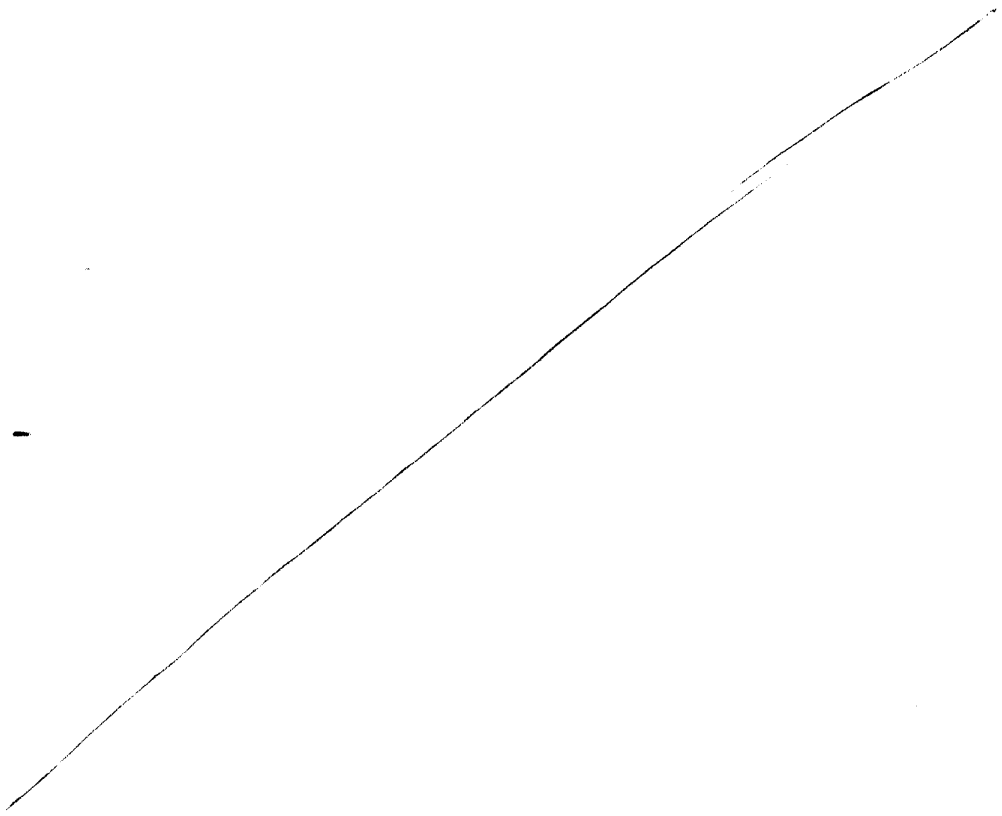
National Laboratory Certification Program

December 13, 2000

296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

The enclosed critique was developed from the inspection report associated with the November 01, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in 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:



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 listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. 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. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt296

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0296
Document No. Final

Laboratory: S.E.D. Medical Laboratories

Location: Albuquerque, NM

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 1 November 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

January 11, 2001

Deborah J. Denson
NLCP Inspection Analyst
Research Triangle Institute
3040 Cornwallis Rd.
P.O. Box 12194
Research Triangle Park, North Carolina 27709-2194

S.E.D. Medical Laboratories

5601 Office Blvd., NE
Albuquerque, New Mexico 87109-5816
505-727-6300 800-999-LABS
Fax 505-727-6205

The enclosed is in response to your critique of our laboratory as a result of our special validity test inspection under the National Laboratory Certification Program (NLCP), which we received on December 14, 2000.

Sincerely,

Martin J. Brady
Director of Toxicology
S.E.D. Medical Laboratories

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 23, 2001

0296
Mr. Martin J. Brady
S.E.D. Medical Laboratories
5601 Office Blvd.
Albuquerque, NM 87109

Dear Mr. Brady:

We have reviewed the material provided in your correspondence of January 11, 2001 submitted in response to issues raised during the November 01, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 13, 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:

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

Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that its specimen validity testing procedures are in compliance with program guidance. All corrective actions must be implemented within 30 days of the receipt of this correspondence and 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT296