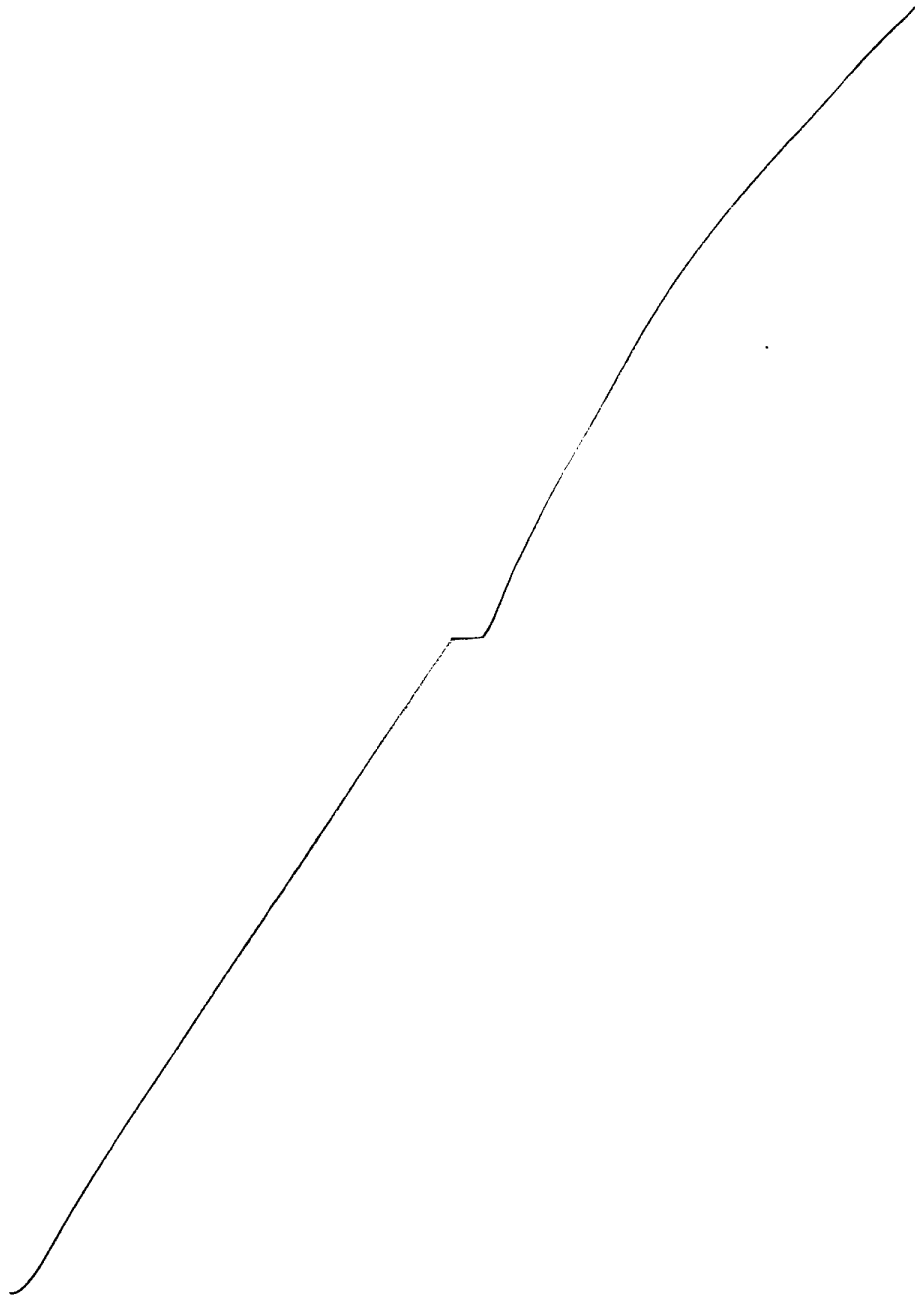


Validity Testing Information Part I

Laboratory Name: American Medical Laboratories, Inc.
Address: 14225 Newbrook Drive, Chantilly, VA 20153
Responsible Person: Anthony Costantino (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

10/15/98

Date

ANTHONY COSTANTINO
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

10/15/00

Date

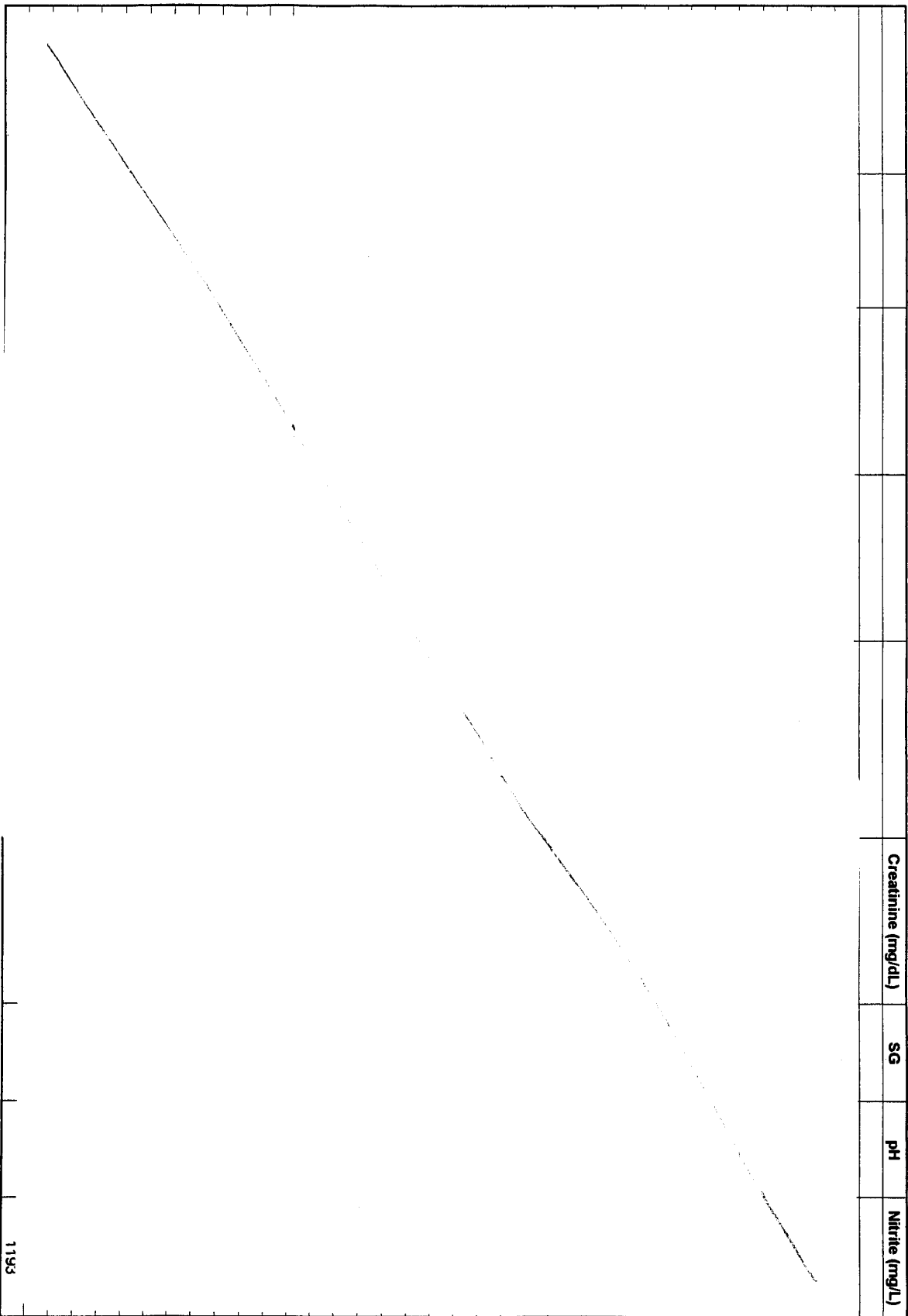
Anthony Costantino

Printed Name, Responsible Person

American Medical Laboratories, Inc
14225 Newbrook Drive
Chantilly, VA 20153

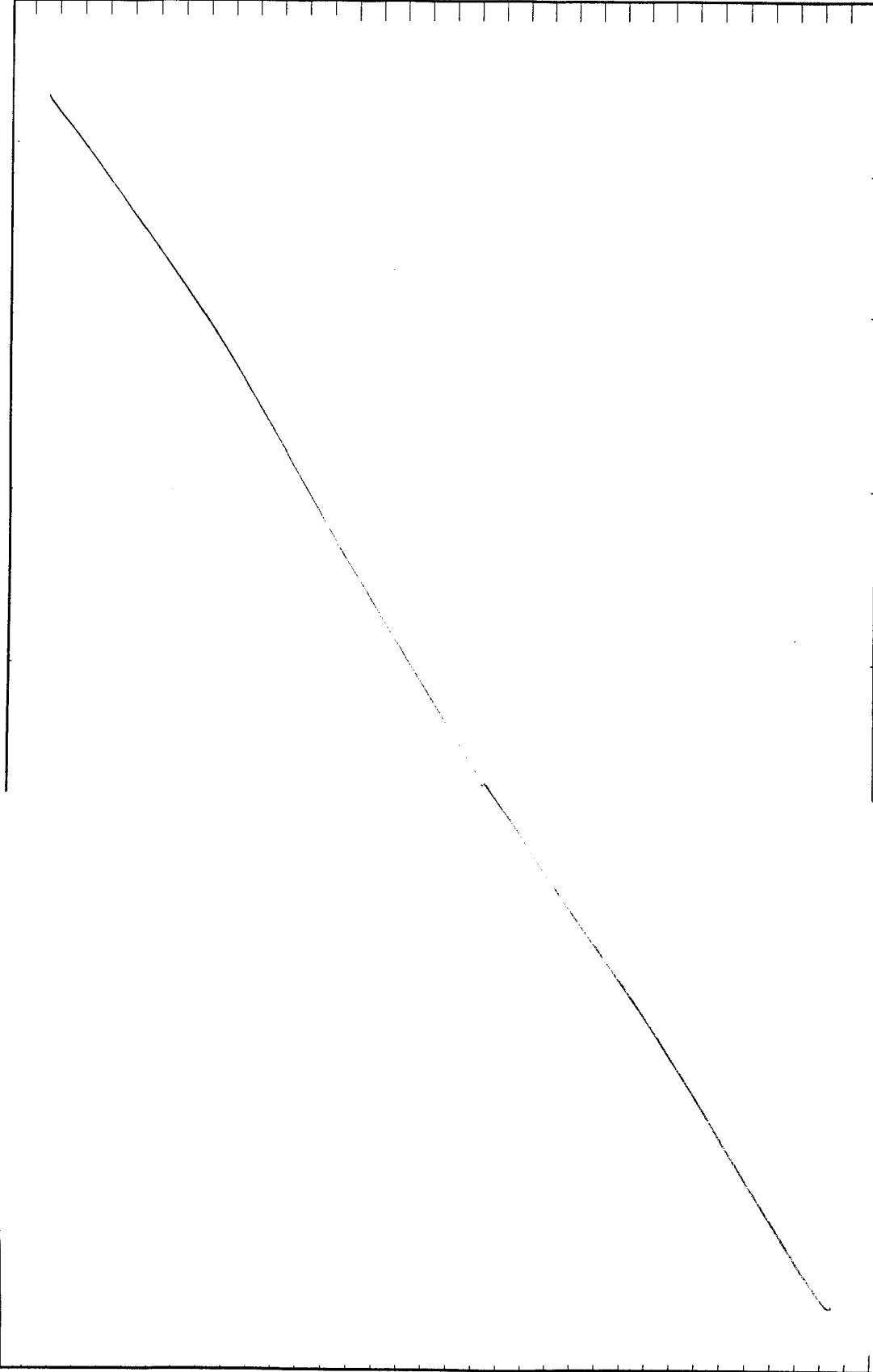
Specimen ID	Accession	Date Received	Date Reported	Reported Result	Creatinine (mg/dL)	SG	pH	Nitrite (mg/L)

American Medical Laboratories, Inc
14225 Newbrook Drive
Chantilly, VA 20153



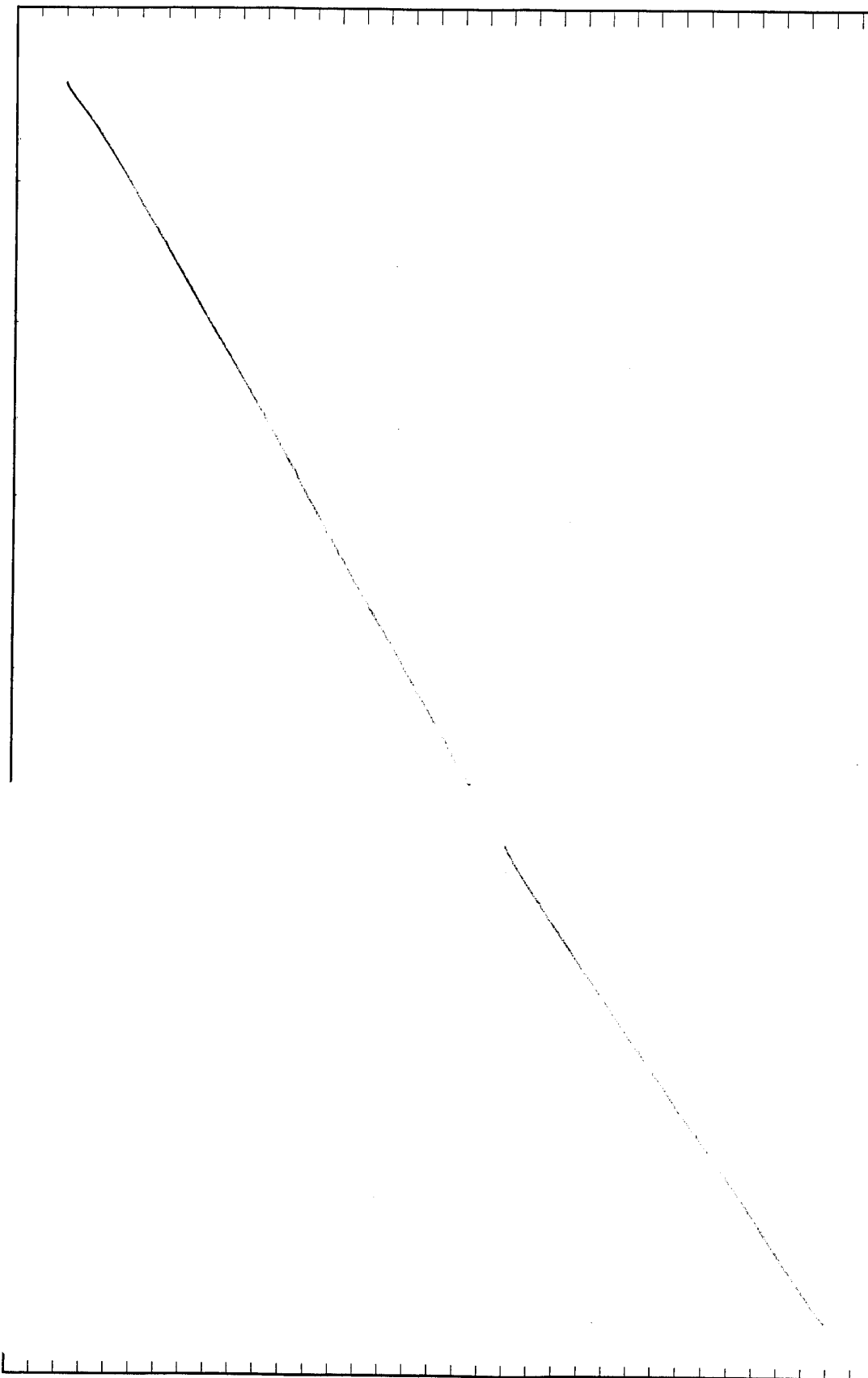
American Medical Laboratories, Inc
14225 Newbrook Drive
Chantilly, VA 20153

Specimen ID	Accession	Date Received	Date Reported	Reported Result	Creatinine (mg/dL)	SG	pH	Nitrite (mg/L)



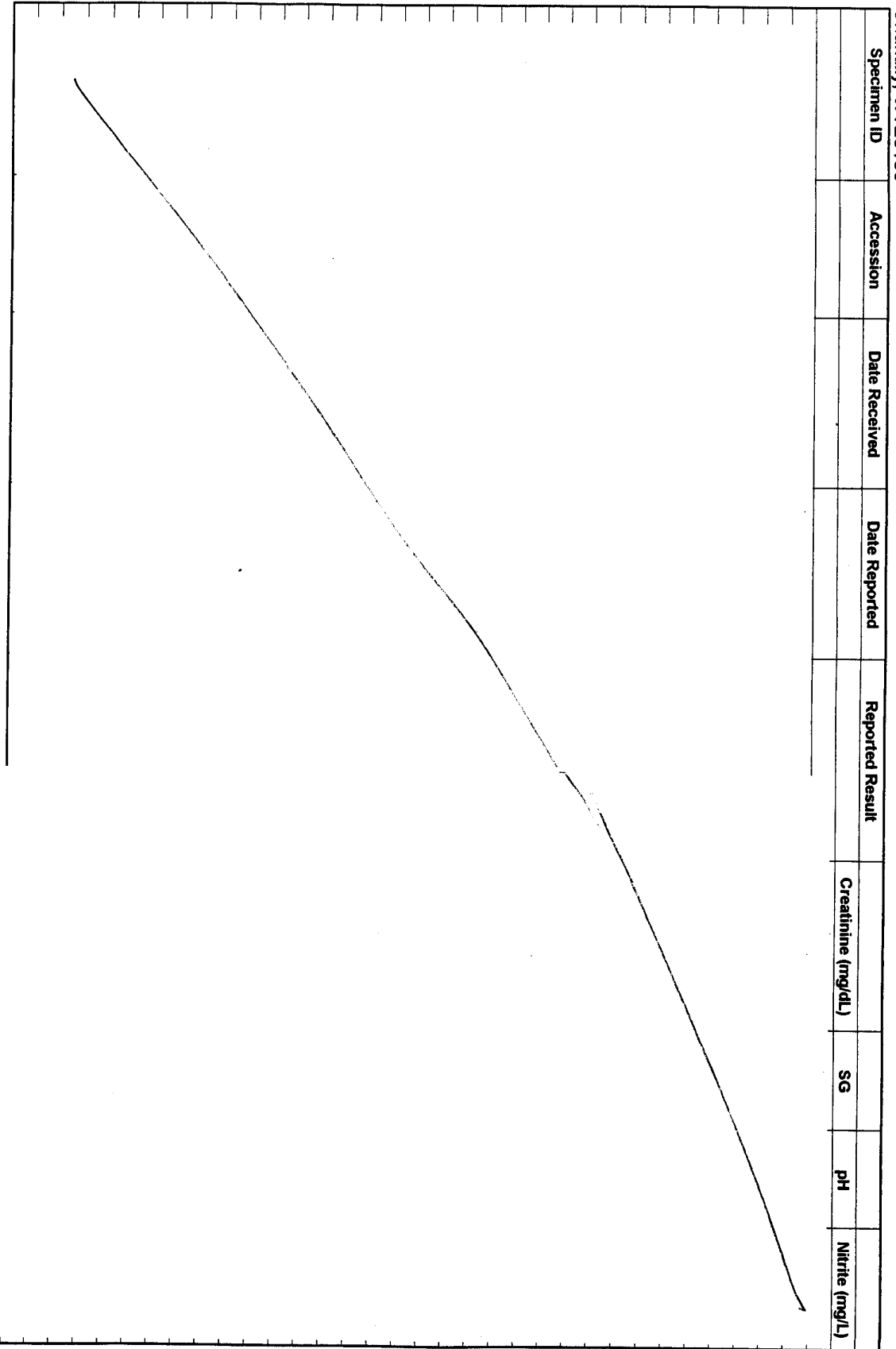
American Medical Laboratories, Inc
14225 Newbrook Drive
Chantilly, VA 20153

Specimen ID	Accession	Date Received	Date Reported	Reported Result	Creatinine (mg/dL)	SG	pH	Nitrite (mg/L)



American Medical Laboratories, Inc
14225 Newbrook Drive
Chantilly, VA 20153

Specimen ID	Accession	Date Received	Date Reported	Reported Result	Creatinine (mg/dL)	SG	pH	Nitrite (mg/L)





RESEARCH TRIANGLE INSTITUTE

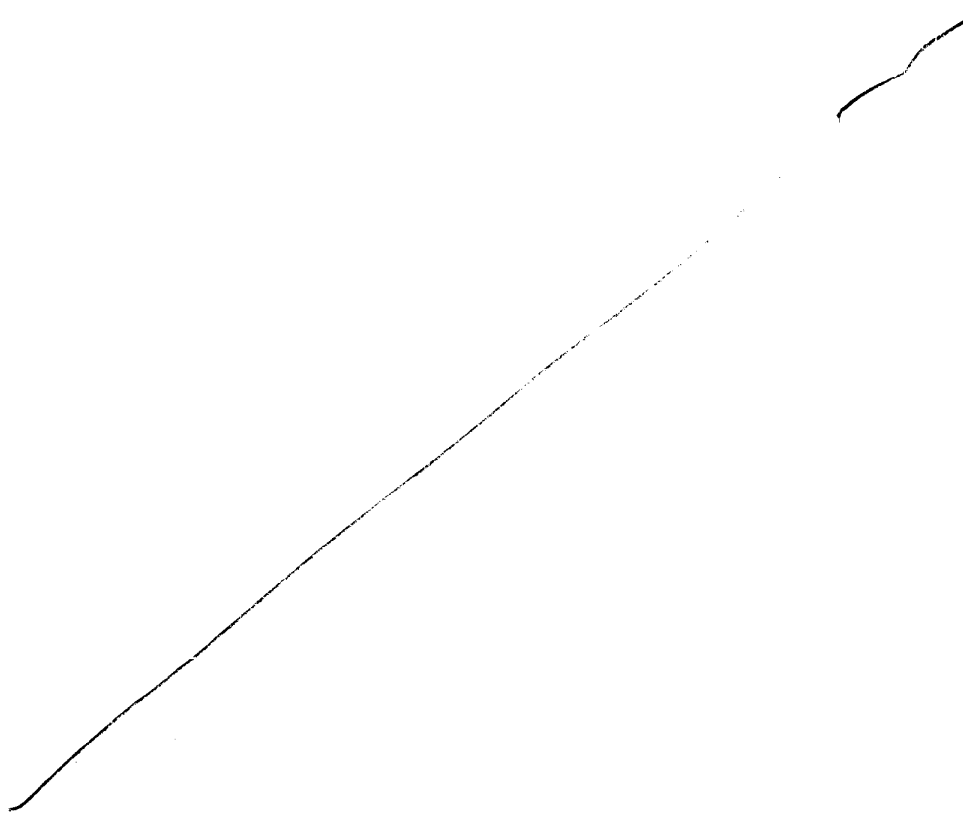
National Laboratory Certification Program

December 15, 2000

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

The enclosed critique was developed from the inspection report associated with the November 15, 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:



Dr. Costantino
December 15, 2000
Page 2 of 2

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
NLCP Technical Analyst

Enclosure

cc: Project Files/svt037

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0037
Document No. Final

Laboratory: American Medical Laboratories, Inc.

Location: Chantilly, VA

Document Reviewed: Specimen Validity Testing Inspection Report

Date: 15 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



AMERICAN MEDICAL LABORATORIES, INC.®

14225 Newbrook Drive
Post Office Box 10841
Chantilly, VA 20153-0841
703-802-6900

received
1/22/01 DD



January 18, 2001

Deborah J. Denson
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, NC 27709-2194

Dear Ms. Denson:

The enclosed documentation is in response to the critique associated with the November 15, 2000 specimen validity testing inspection performed at this laboratory. All attachments are organized in accordance with the sections and item numbers in the letter and critique. The issues raised in the letter are addressed first followed by those items listed in the critique that are not in the letter. All corrective actions have been implemented.

[Redacted]

The following addresses items listed in the critique that were not addressed above.

Section E. Standard Operating Procedures:

[Redacted]

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

[Redacted]

Section I. Specimen Validity Tests:

[Redacted]

If you would like additional information please call me at 800-336-3718 EXT. 6028

Sincerely,

A handwritten signature in black ink, appearing to read 'AG Costantino', written in a cursive style.

Anthony G. Costantino

RESEARCH TRIANGLE INSTITUTE



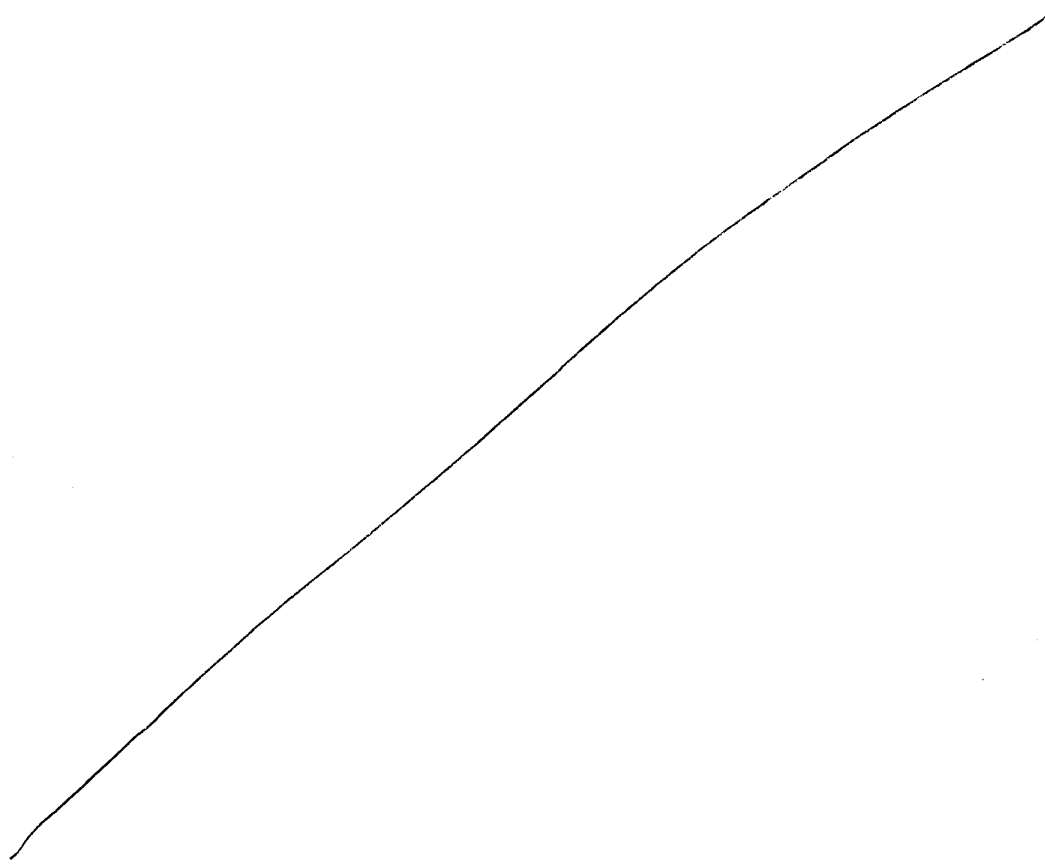
National Laboratory Certification Program

January 30, 2001

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

We have reviewed the material provided in your correspondence of January 18, 2001 submitted in response to issues raised during the November 15, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 15, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions are being taken to address the issues raised. However, the following issues require additional clarification and corrective action. The following is a review of the material submitted:



Dr. Costantino
January 30, 2001
Page 2 of 2

The laboratory must submit, within 10 calendar days of receipt of this letter, documentation of corrective actions addressing the issues listed in this correspondence. 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 or referral to The Department of Transportation for Public Interest Exclusion action.***

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

cc: Project Files/SVT037



AMERICAN MEDICAL LABORATORIES, INC.®

14225 Newbrook Drive
Post Office Box 10841
Chantilly, VA 20153-0841
703-802-6900

received
02/09/01 DD



February 8, 2001

Deborah J. Denson
3040 Cornwallis Road
RTP, NC 27709

Dear Ms. Denson:

This letter is in response to your correspondence dated January 30, 2001 regarding the specimen validity testing inspection critique. The issues that were raised are described in the order that they appeared in your letter.

If you have any questions or if I can be of further assistance please contact me at (703) 802-6900 Ext. 6028.

Sincerely,

Anthony G. Costantino, Ph.D.

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

February 15, 2001

0037
Dr. Anthony G. Costantino
American Medical Laboratories, Inc.
14225 Newbrook Drive
P.O. Box 10841
Chantilly, VA 20151

Dear Dr. Costantino:

We have reviewed the material provided in your correspondence of February 08, 2001 submitted in response to issues raised during the November 15, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of January 30, 2001. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:

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,

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

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT037

