11

Validity Testing Information Part I

Laboratory Name: Laboratory Corporation of America
Address: 4022 W. New Lakes Blvd. Memphis, TN 38118

Responsible Person: Barbara Rowland (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).

Barbara Rowland
Signature, Responsible Person

10-5-00
Date

Barbara Rowland
Printed Name, Responsible Person

Frank Wallace

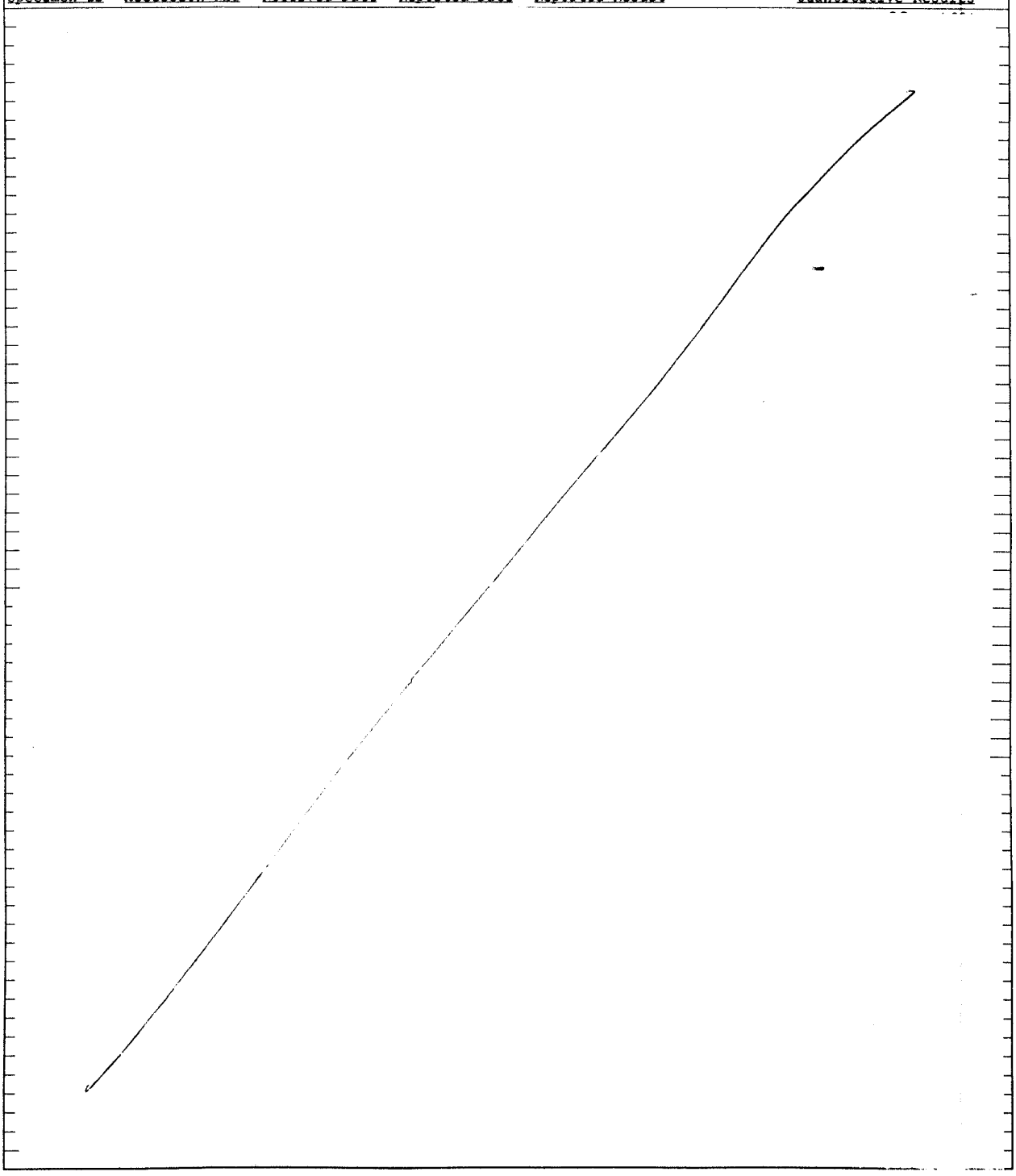
From: "Barbara Rowland" <Barbara_Rowland@labcorp.com>
To: <fnw@rti.org>
Sent: Tuesday, October 17, 2000 1:14 PM
Attach: LabCorp Memphis HP3000 Adulteration Audit.xls; LabCorp Memphis Vax Adulteration Audit.xls
Subject: Adulteration audit

Hi Frank
Here are the spreadsheets from the LabCorp Memphis laboratory.
Thanks Barbara

Adulterated or Substituted DOT Samples since 09/28/1998

Company - Laboratory Corporation of America Holdings / Lab - Memphis

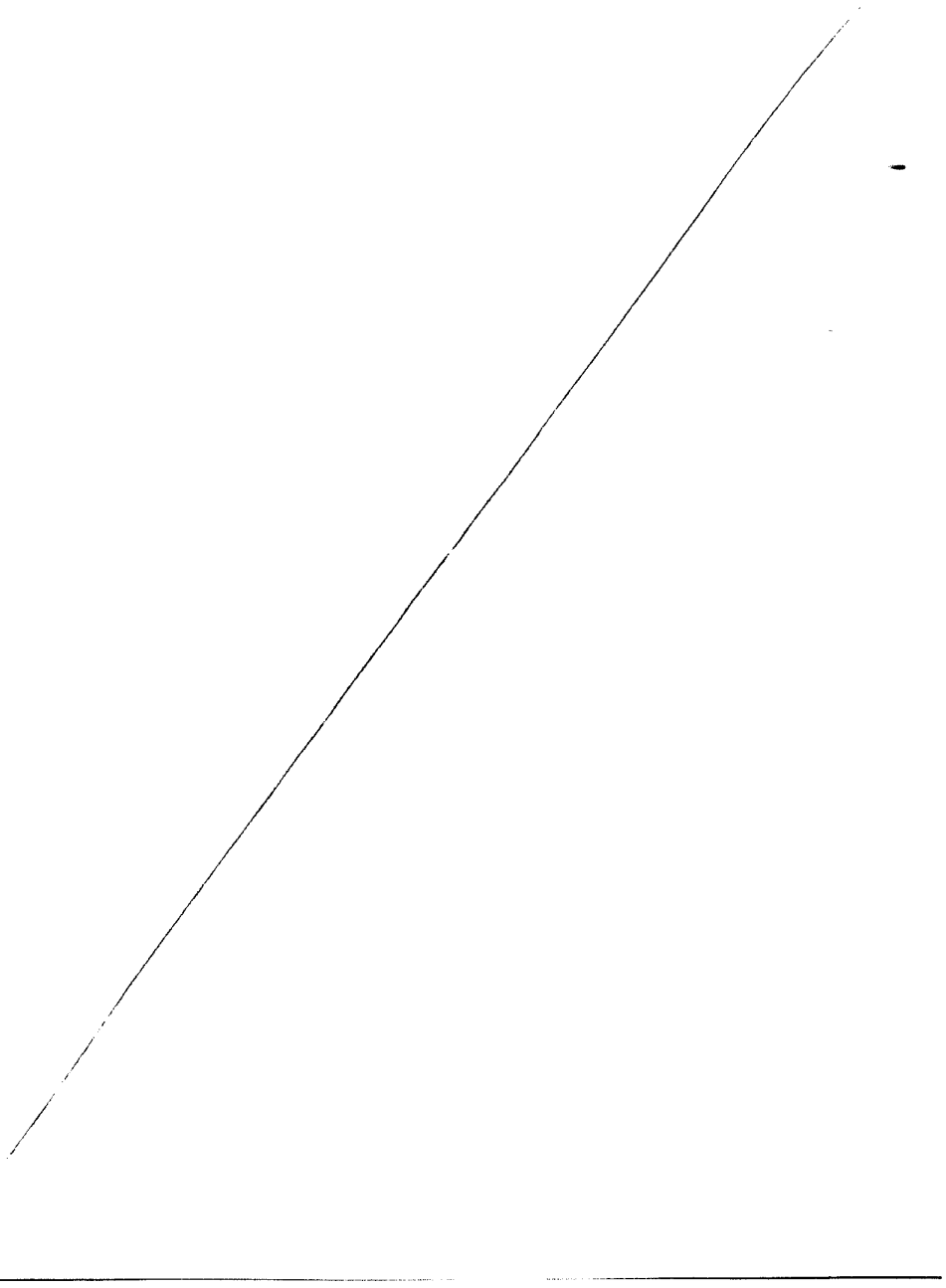
Specimen ID	Accession Nbr	Received Date	Reported Date	Reported Result	Quantitative Results



Adulterated or Substituted DOT Samples since 09/28/1998

Company - Laboratory Corporation of America Holdings / Lab - Memphis

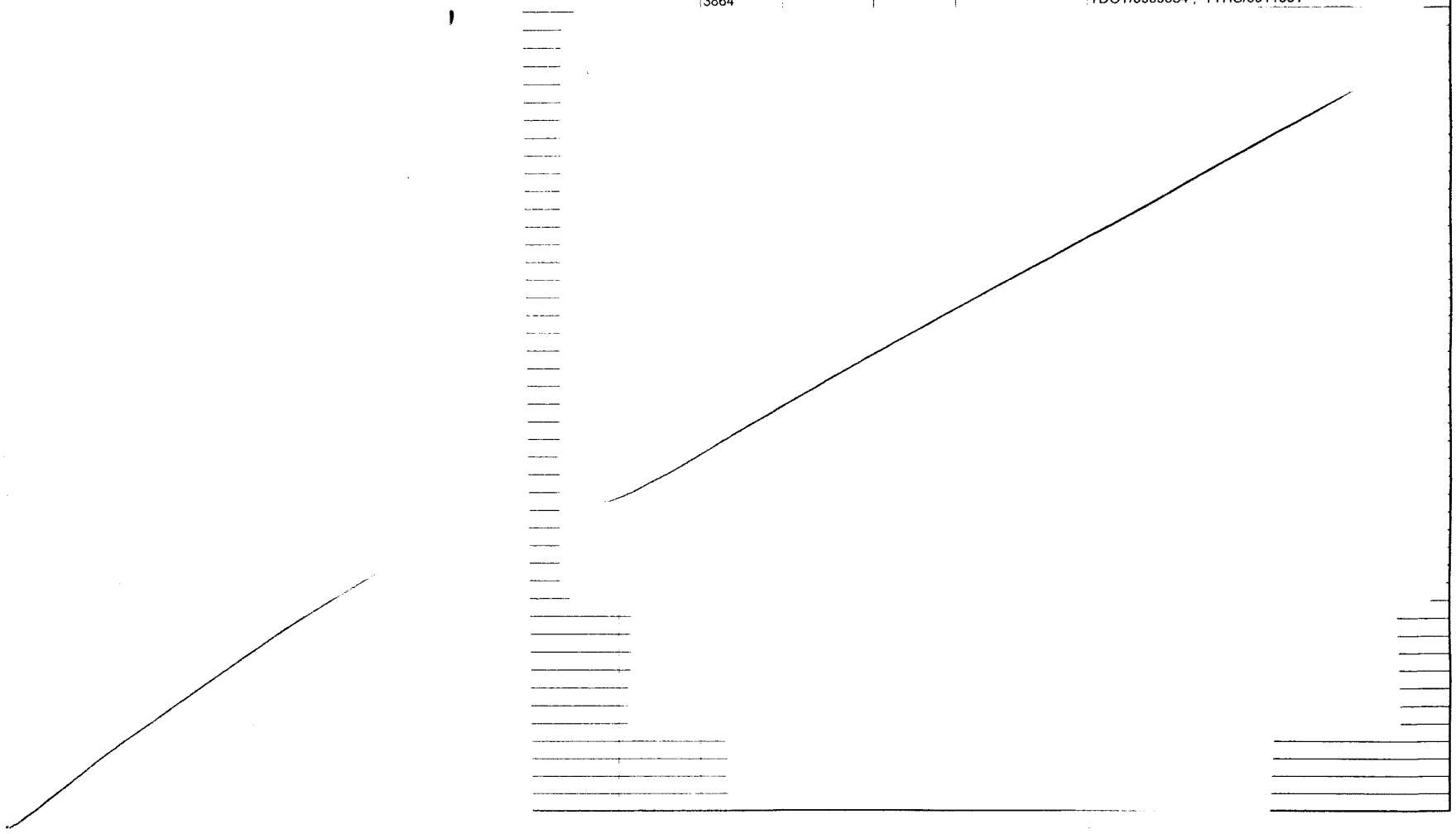
Specimen ID	Accession Nbr	Received Date	Reported Date	Reported Result	Quantit...



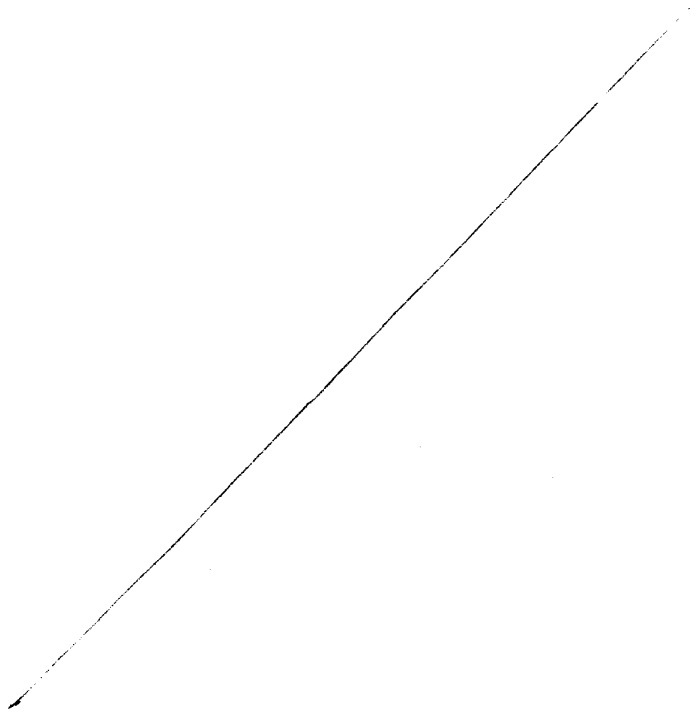
Adulterated or Substituted DOT Samples since 09/28/1998					
Company - Laboratory Corporation of America Holdings / Lab - Memphis					
Specimen ID	Accession Nbr	Received Date	Reported Date	Reported Result	Quantitative Results

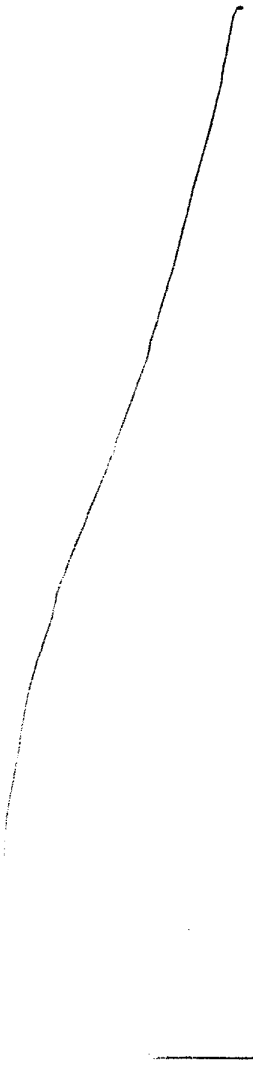
LabCorp OTS - Memphis
Adulterated or Substituted DOT Samples Since 09/01/1998
Company - Laboratory Corporation of America Holdings / Lab - Memphis
Tests Performed on Memphis Vax

Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde	
							3864				TDOT/0909054 , TTHC/0911001



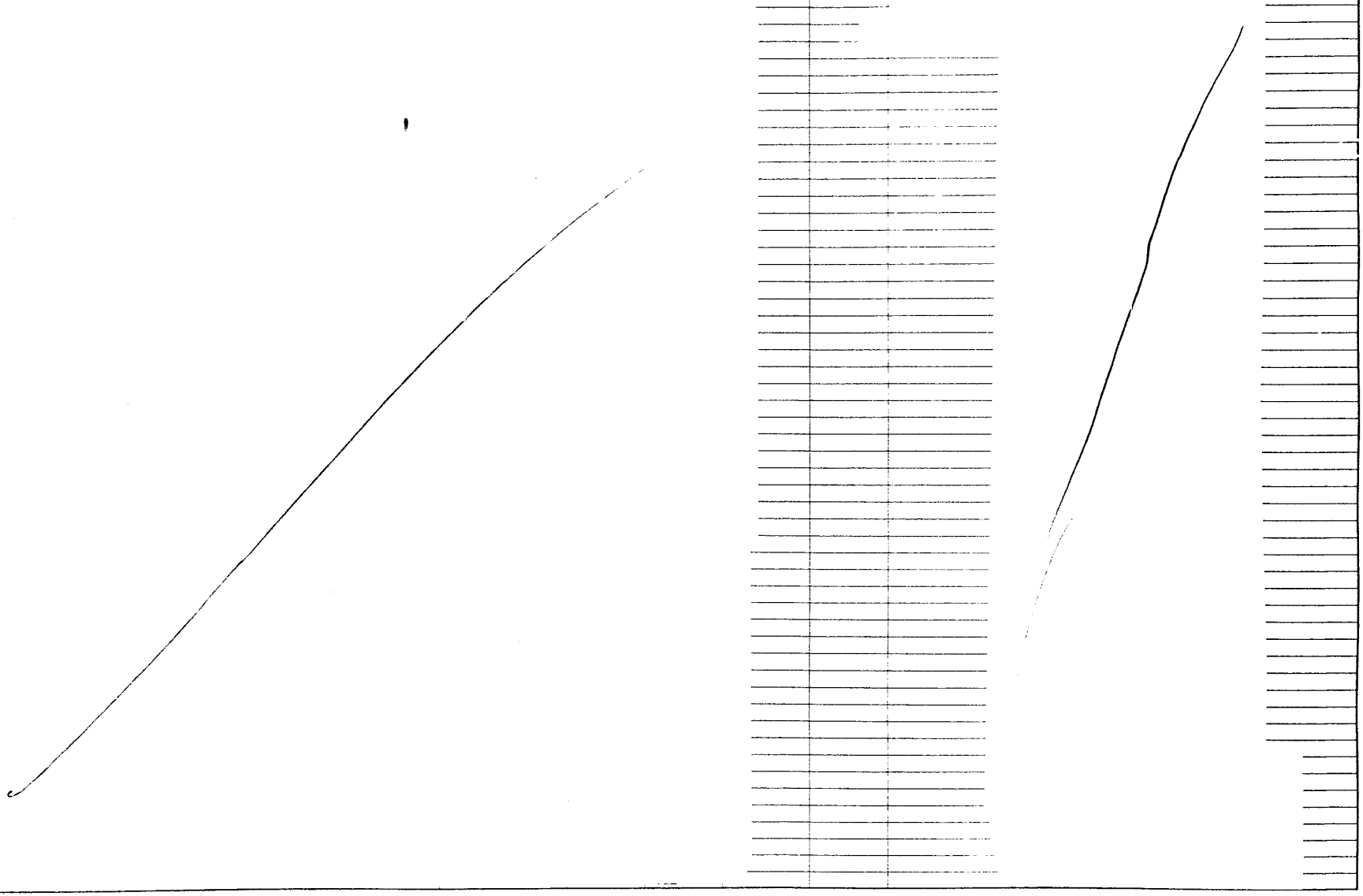
Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde



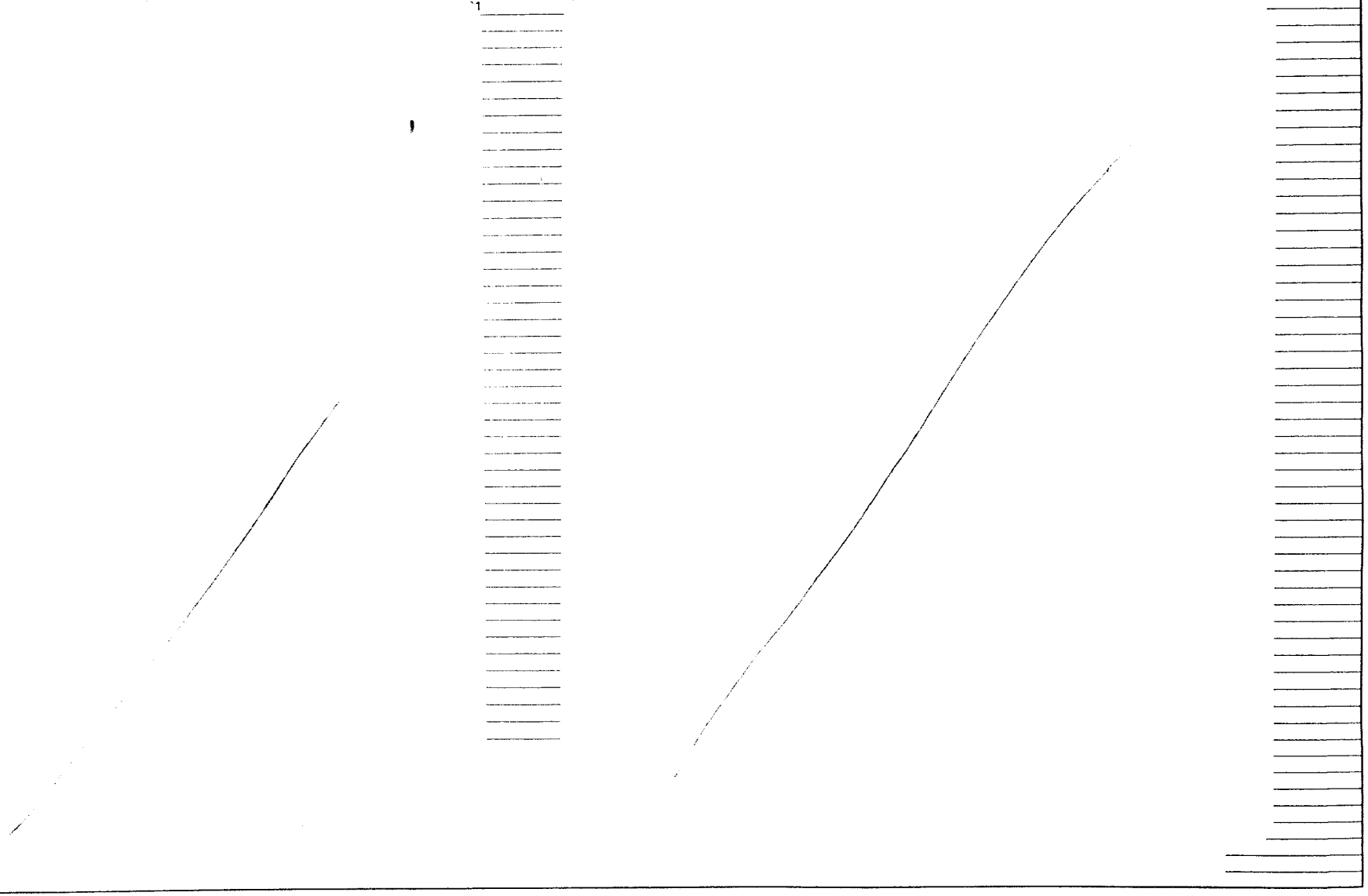


Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde

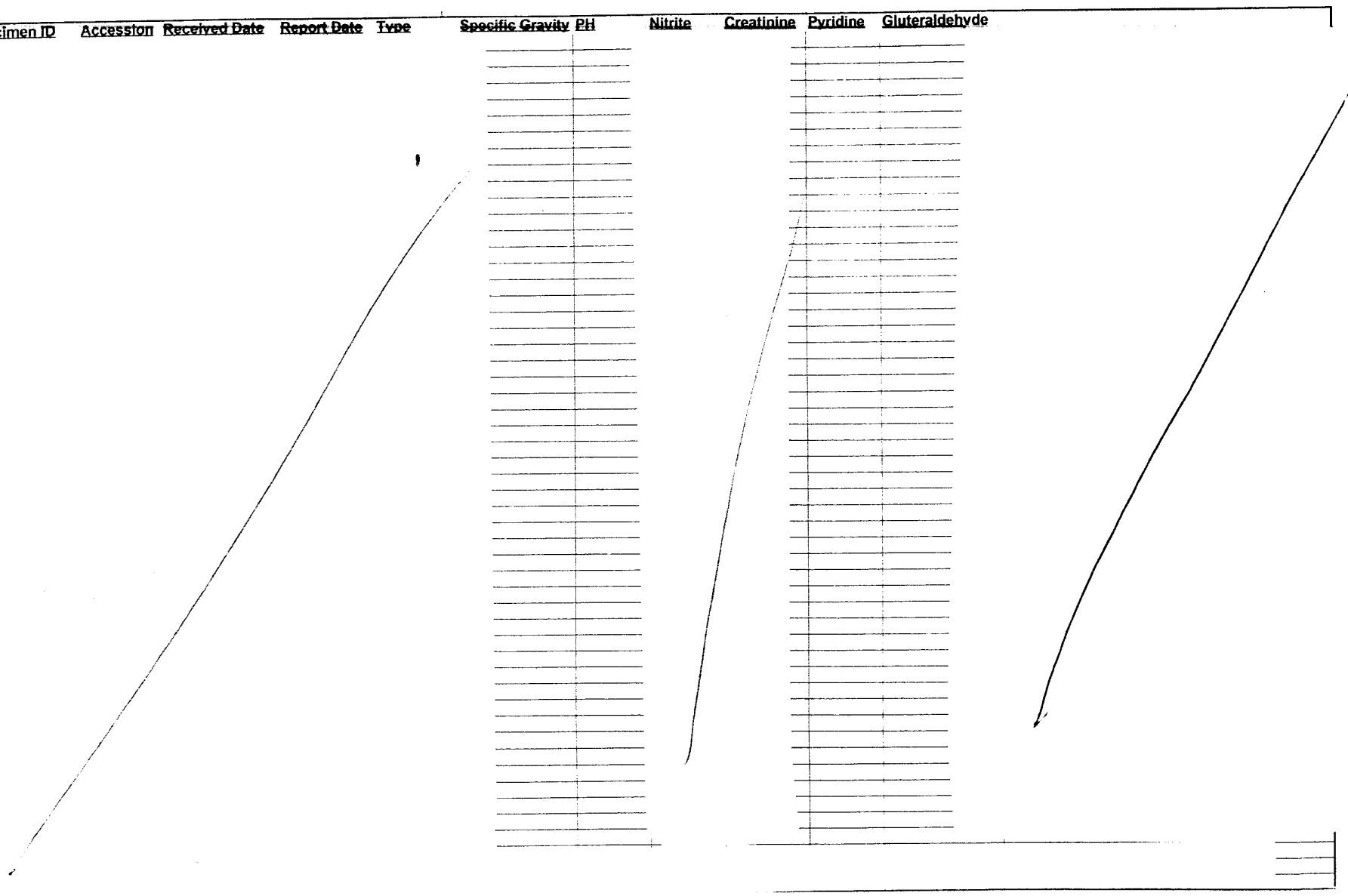
Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde



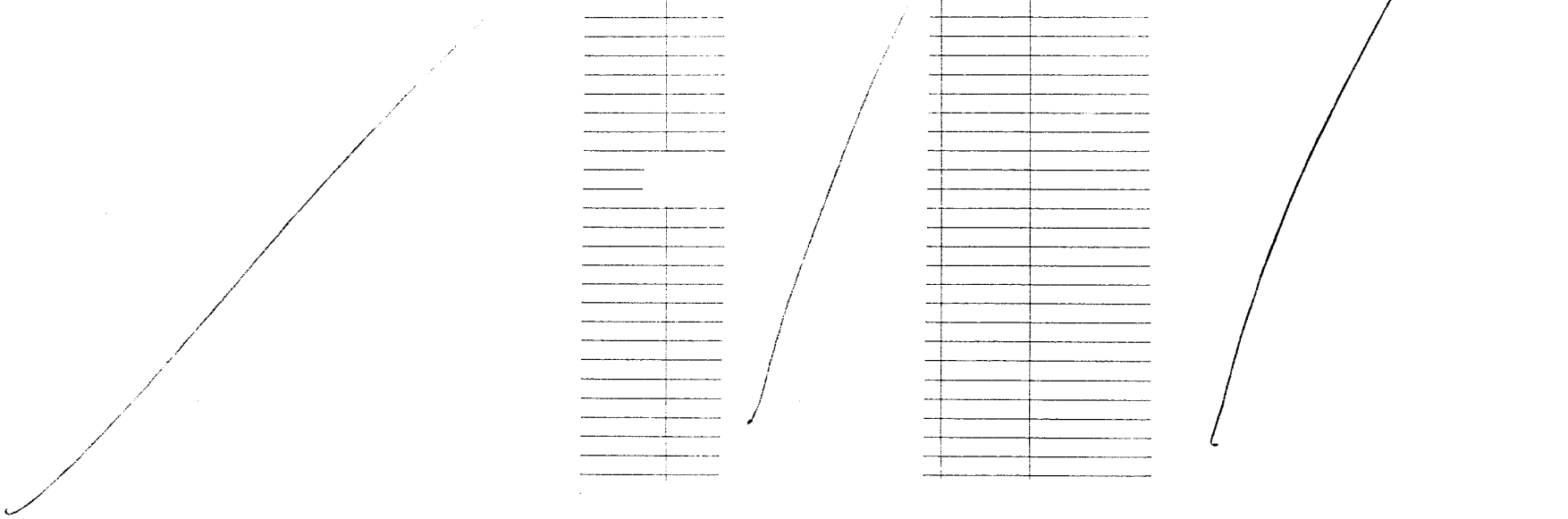
Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde



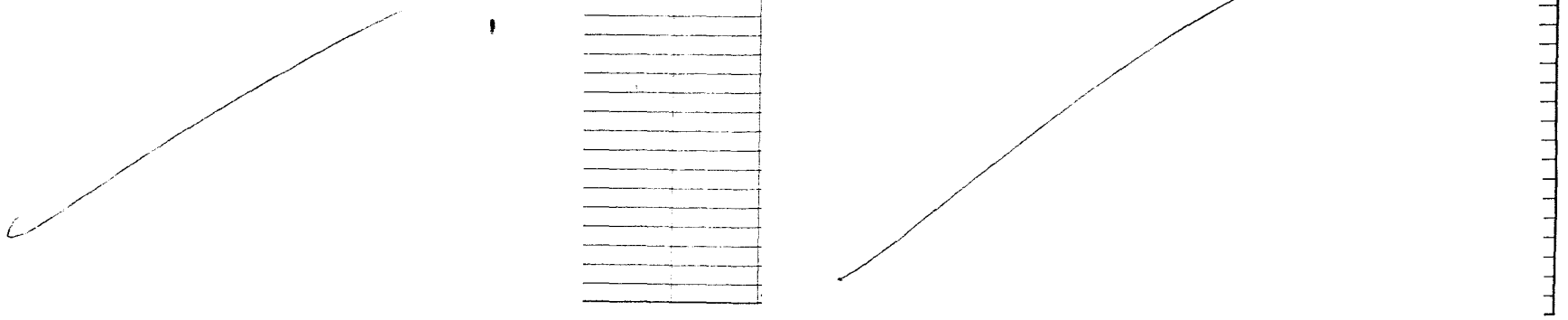
Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde



Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde



Specimen ID	Accession	Received Date	Report Date	Type	Specific Gravity	PH	Nitrite	Creatinine	Pyridine	Gluteraldehyde



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 17, 2000

0249
Ms. Barbara Rowland
Laboratory Corporation of America Holdings
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Ms. Rowland:

The enclosed critique was developed from the inspection report associated with the October 18-20, 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:

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/svt249

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0249
Document No. Final

Laboratory: Laboratory Corporation of America Holdings

Location: Memphis, TN

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 18 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

Section O. Overall

LabCorp
Occupational Testing Services

Laboratory Corporation of America® Holdings
4022 Willow Lake Boulevard
Memphis, Tennessee 38118

Telephone: 901-375-0014
Fax: 901-795-1559

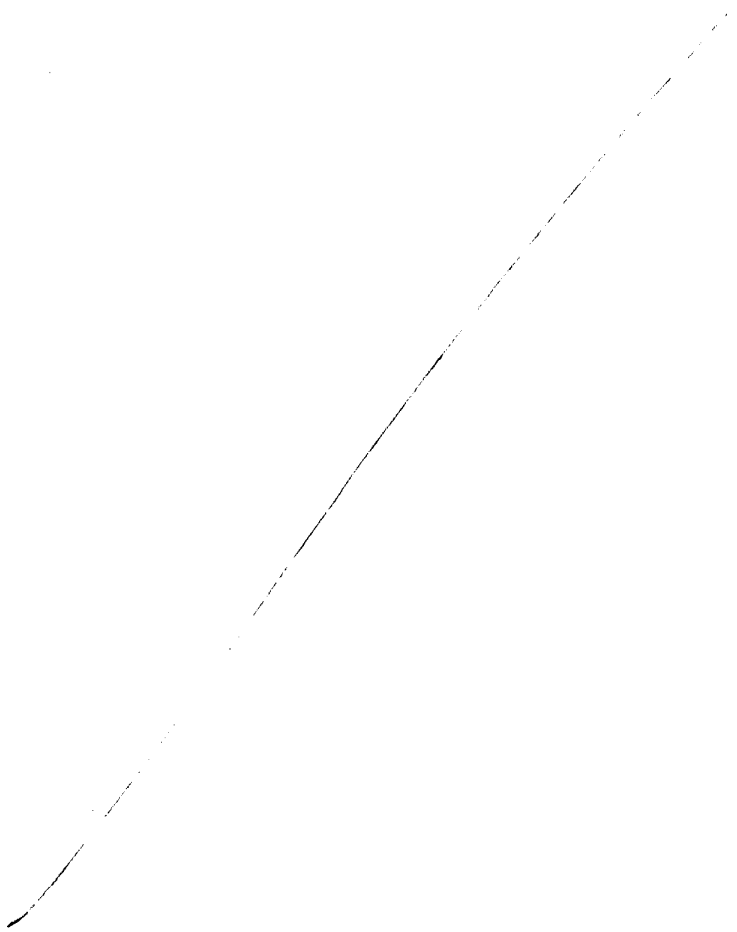
Lab 0249

Dec. 8, 2000

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

Dear Ms. Crumpton,

The following responses and enclosed documents include corrective actions taken in order to address the issues cited from the laboratory's specimen validity testing inspection of October 18-20,2000.



If you have any questions, please call me at 866-827-8042.

Sincerely,

Barbara Rowland, MPA
Responsible Person

RESEARCH TRIANGLE INSTITUTE

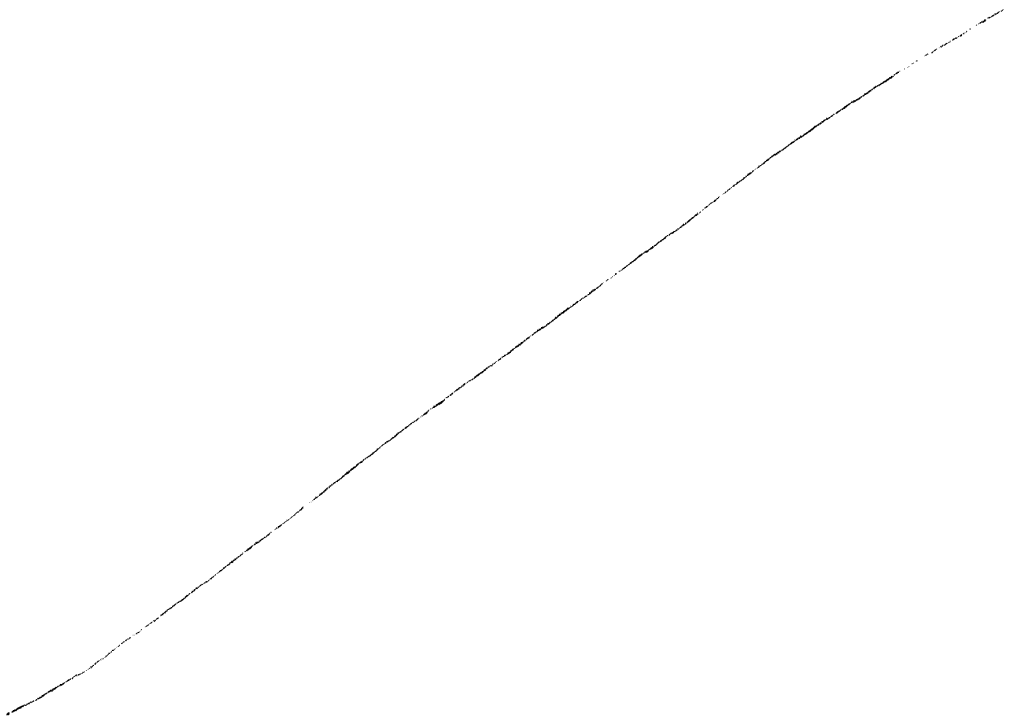
National Laboratory Certification Program

January 5, 2001

0249
Ms. Barbara Rowland
Laboratory Corporation of America Holdings
4022 Willow Lake Blvd.
Box 752110
Memphis, TN 38118

Dear Ms. Rowland:

We have reviewed the material provided in your correspondence of December 8, 2000, submitted in response to issues raised during the October 18-20, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 17, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. The following was noted during our review of submitted material:



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

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 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 R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0249