Validity Testing Information Part I

Laboratory Name: Drug Scan, INC
Address: 1119 Mearns Road, Warminster PA 18974
Richard Cohn
Responsible Person: Mary Lichtenwalner (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).

Mark Lautenwalder — Signature, Responsible Person

10/5/2000 — Date

Mark Lautenwalder — 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).

Mark Lutenwalner, PhD — 13 October 2006

Signature, Responsible Person — Date

Mark Lutenwalner

Printed Name, Responsible Person

DRUGSCAN
Medical and Forensic Toxicology Services

10/13/2000

Kenneth Davis, Jr.
NLCP/RTI Program Director
3040 Cornwallis Road
Research Triangle Park
North Carolina 27709-2194

Dear Mr. Davis

The attached lists (in Excel format) contain data on all DOT regulated specimens reported as adulterated or substituted from 8/1/98 (as far back as records were retrievable) to 10/4/2000 (date of printing of list).

Values are expressed in the following concentration units:

creatinine	mg/dL
nitrite	ug/mL
chromate	ug/mL

Sincerely,

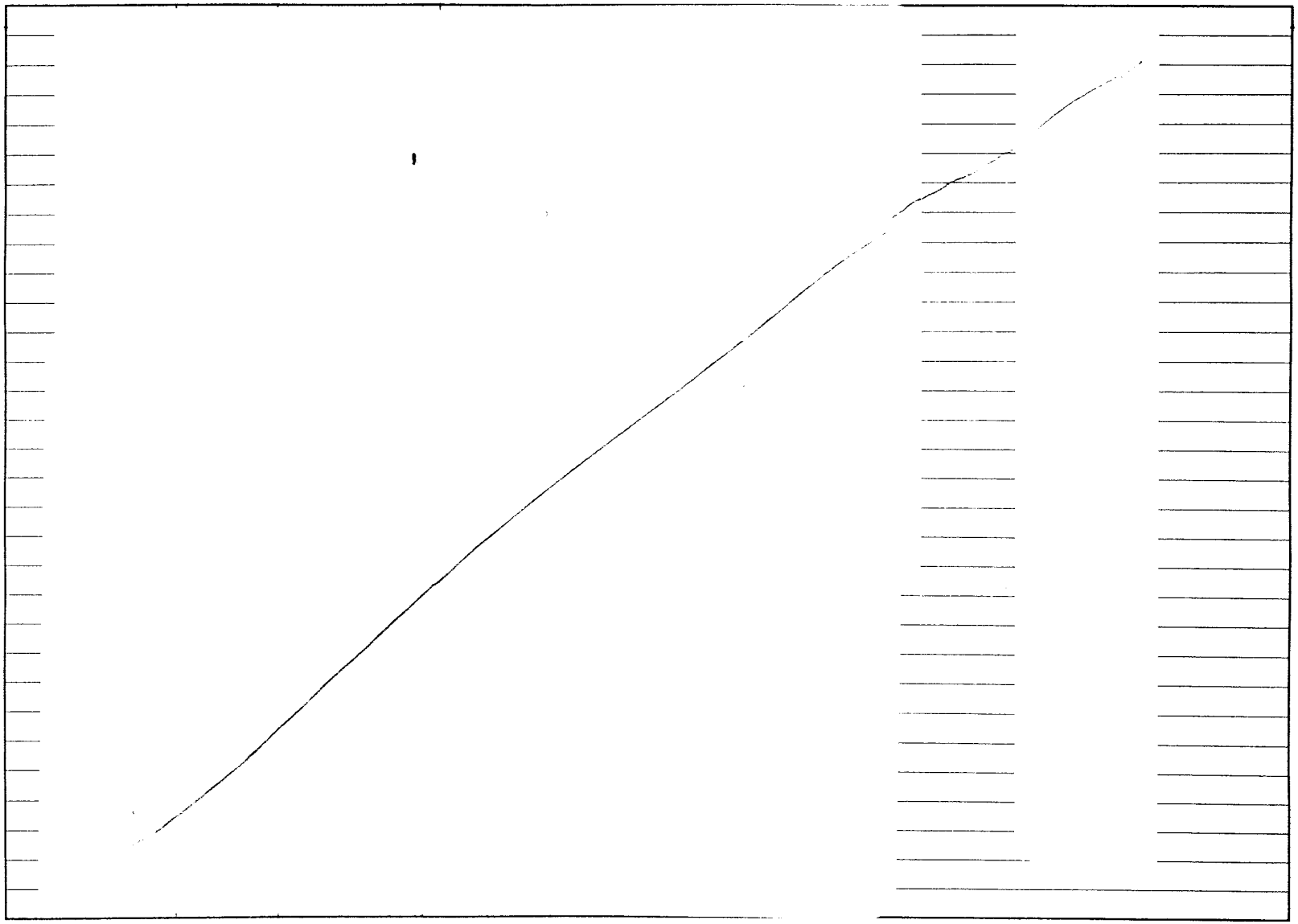
Mark Lichtenwalner
Responsible Person

1119 Mearns Road, P.O. Box 2969, Warminster, PA 18974-0097, Telephone (215) 674-9310

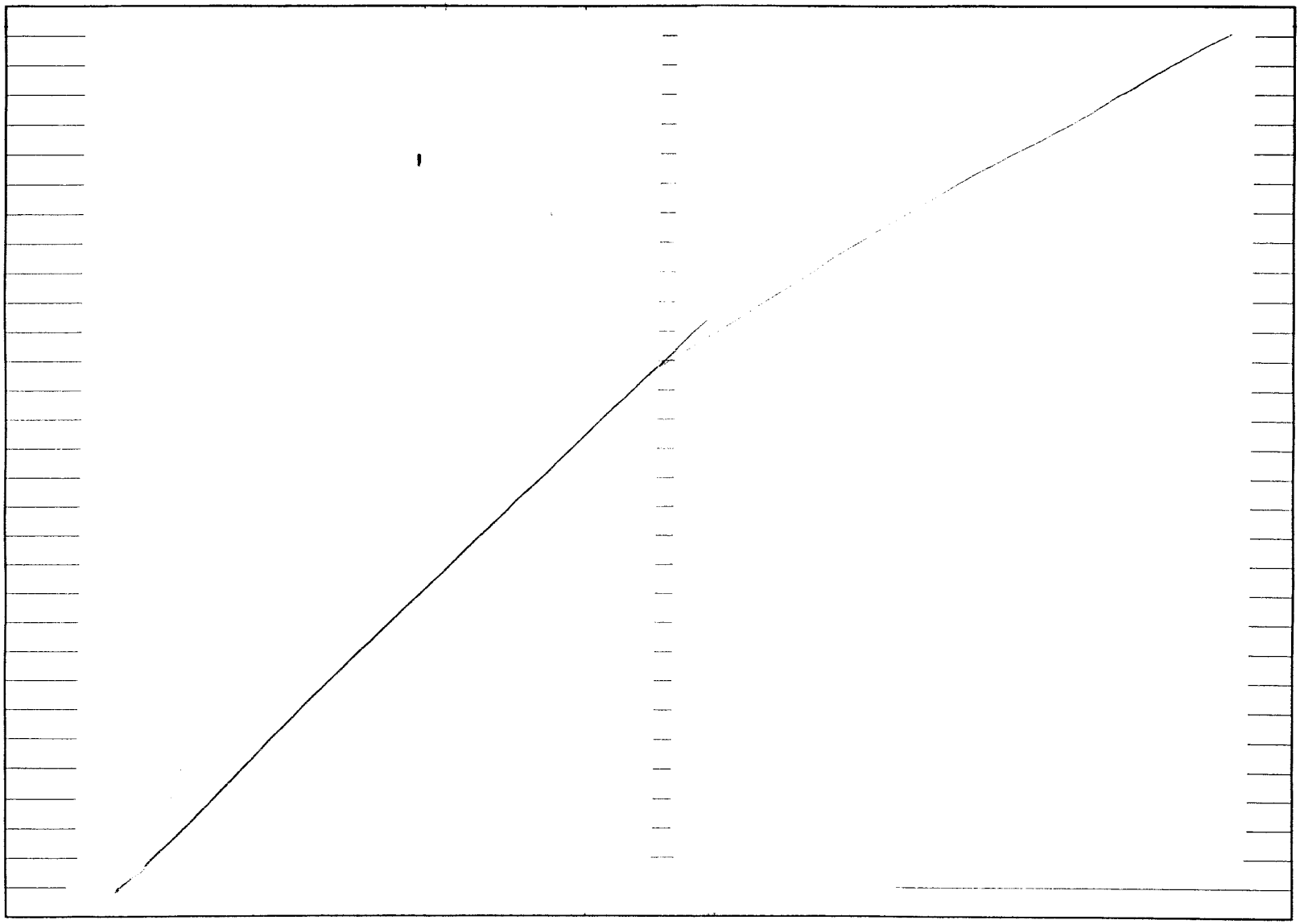
DRUG SCAN - 0224

SPECIMEN ID#	LAN	Date Received	Date Reported	Reported As	Quantitative Results

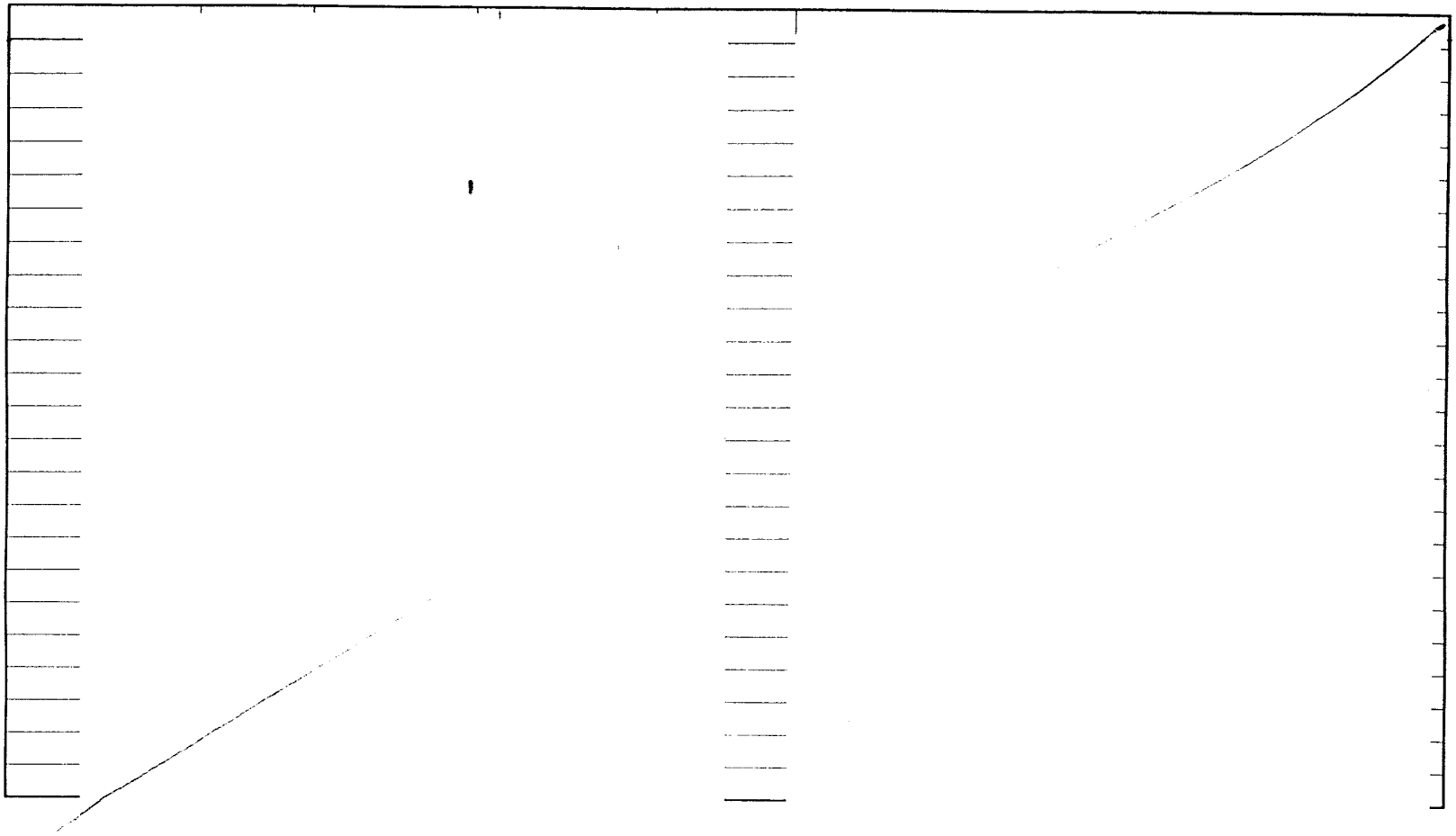
DRUG SCAN - 0224



DRUG SCAN - 0224

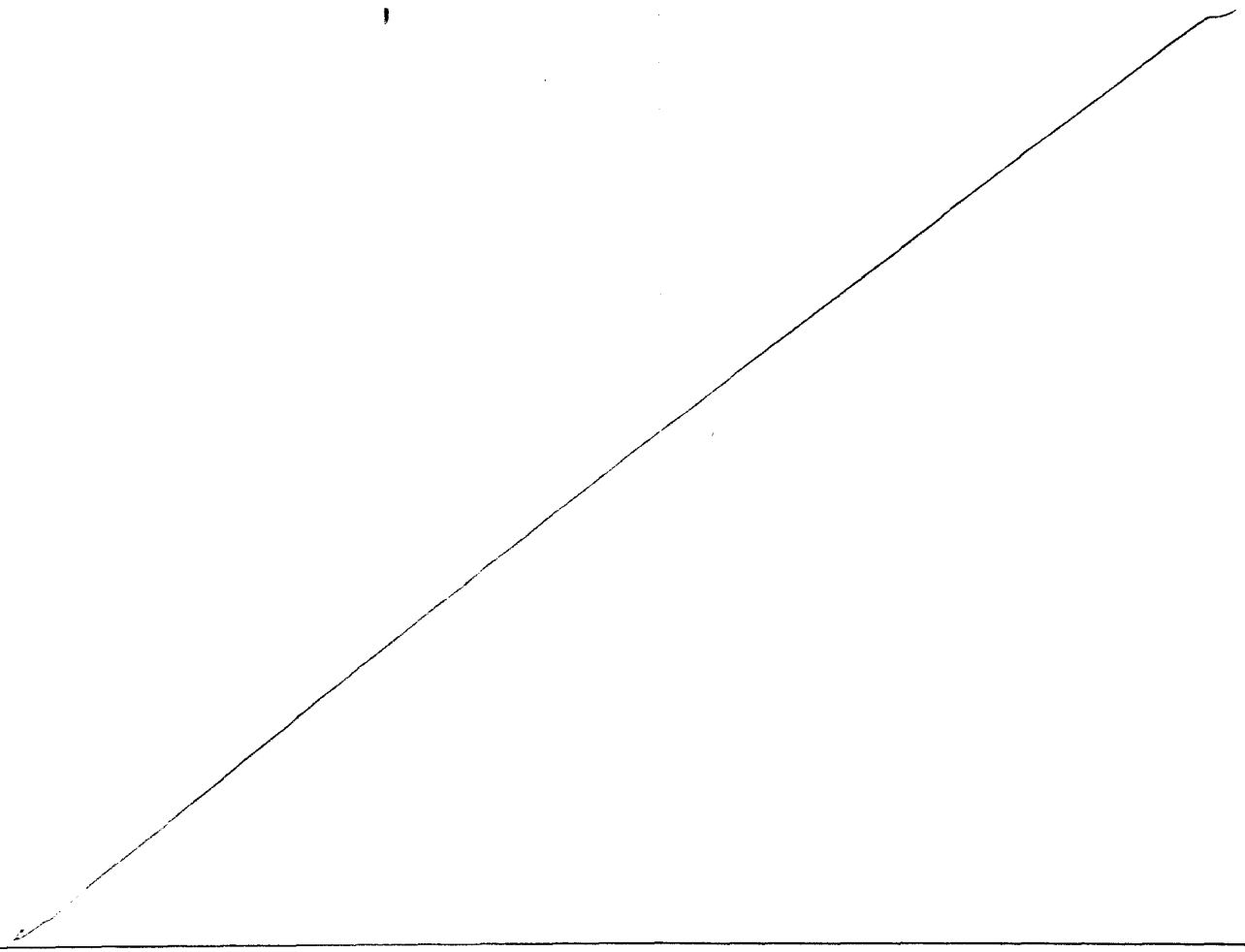


DRUG SCAN - 0224

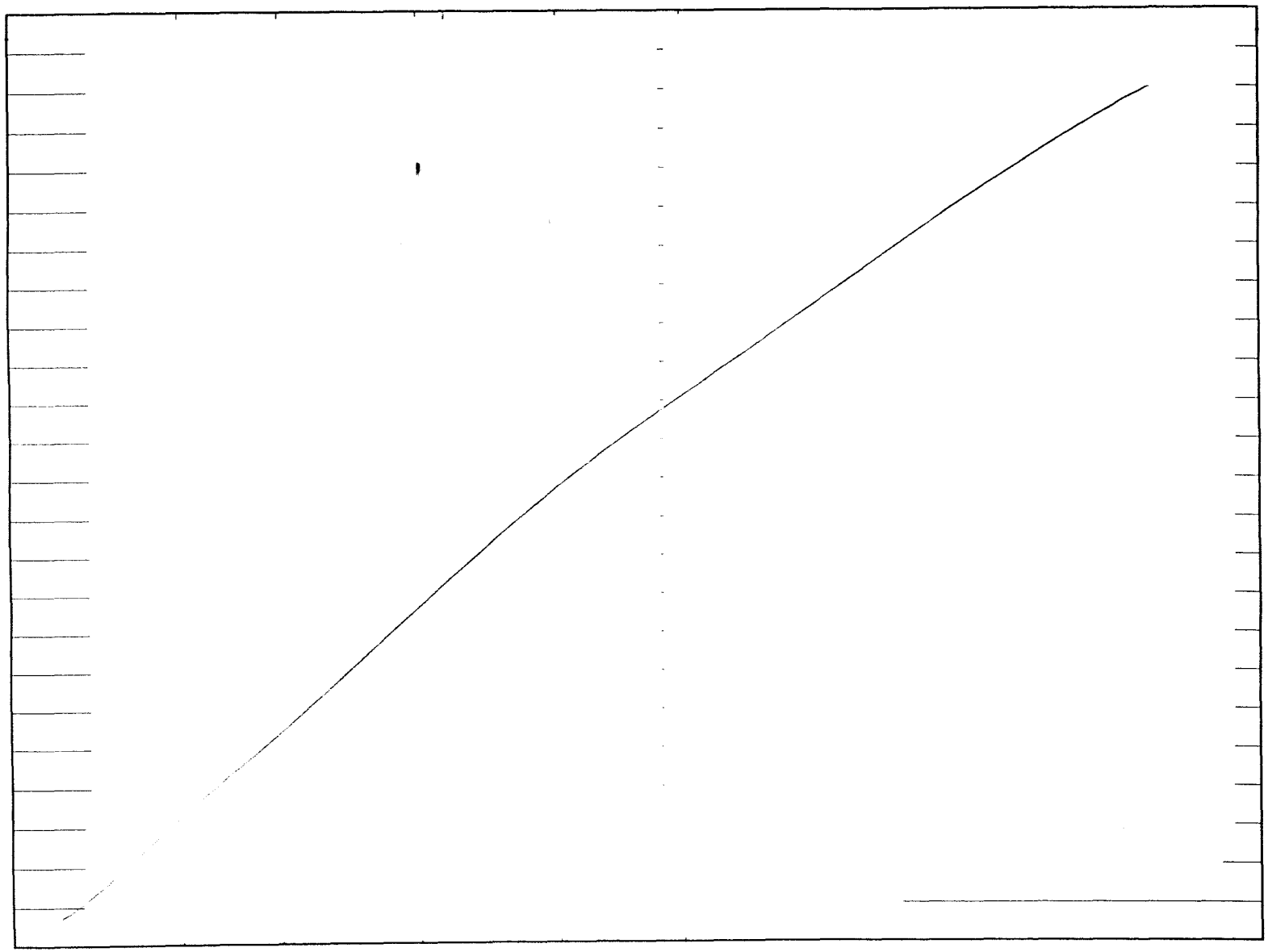


DRUG SCAN - 0224

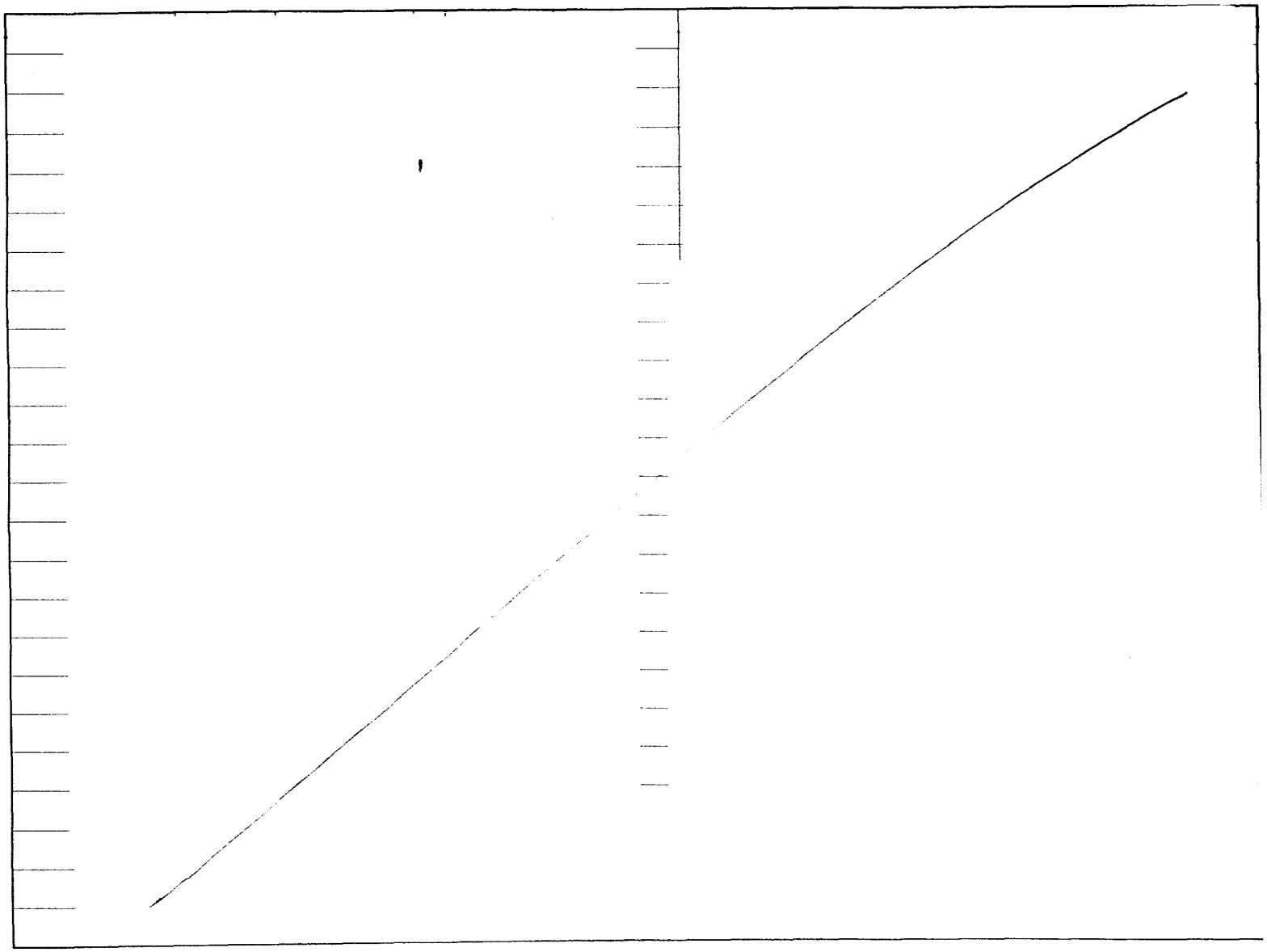
SPECIMEN ID#	LAN	Date Received	Date Reported	Reported As	Quantitative Results



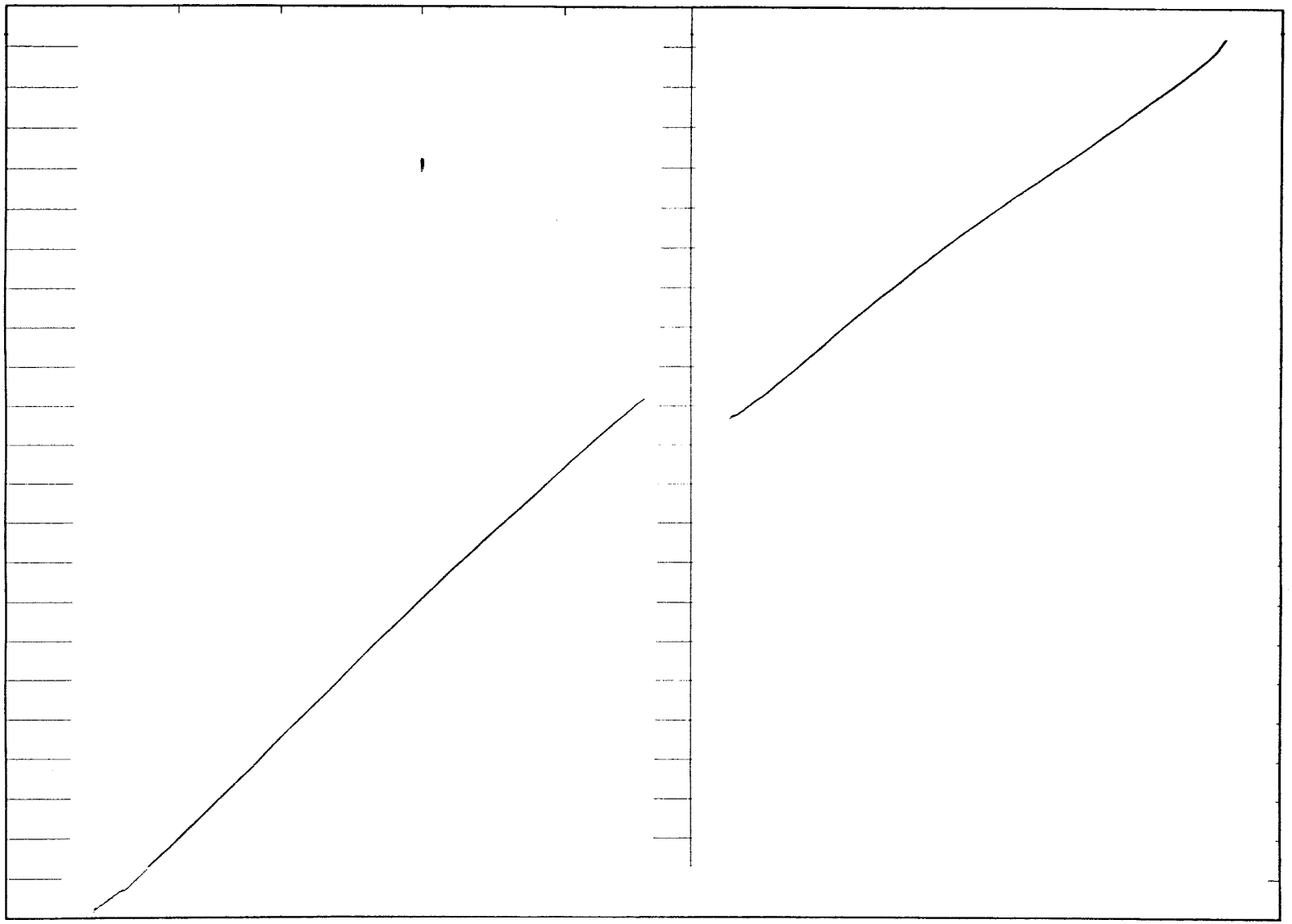
DRUG SCAN - 0224



DRUG SCAN - 0224

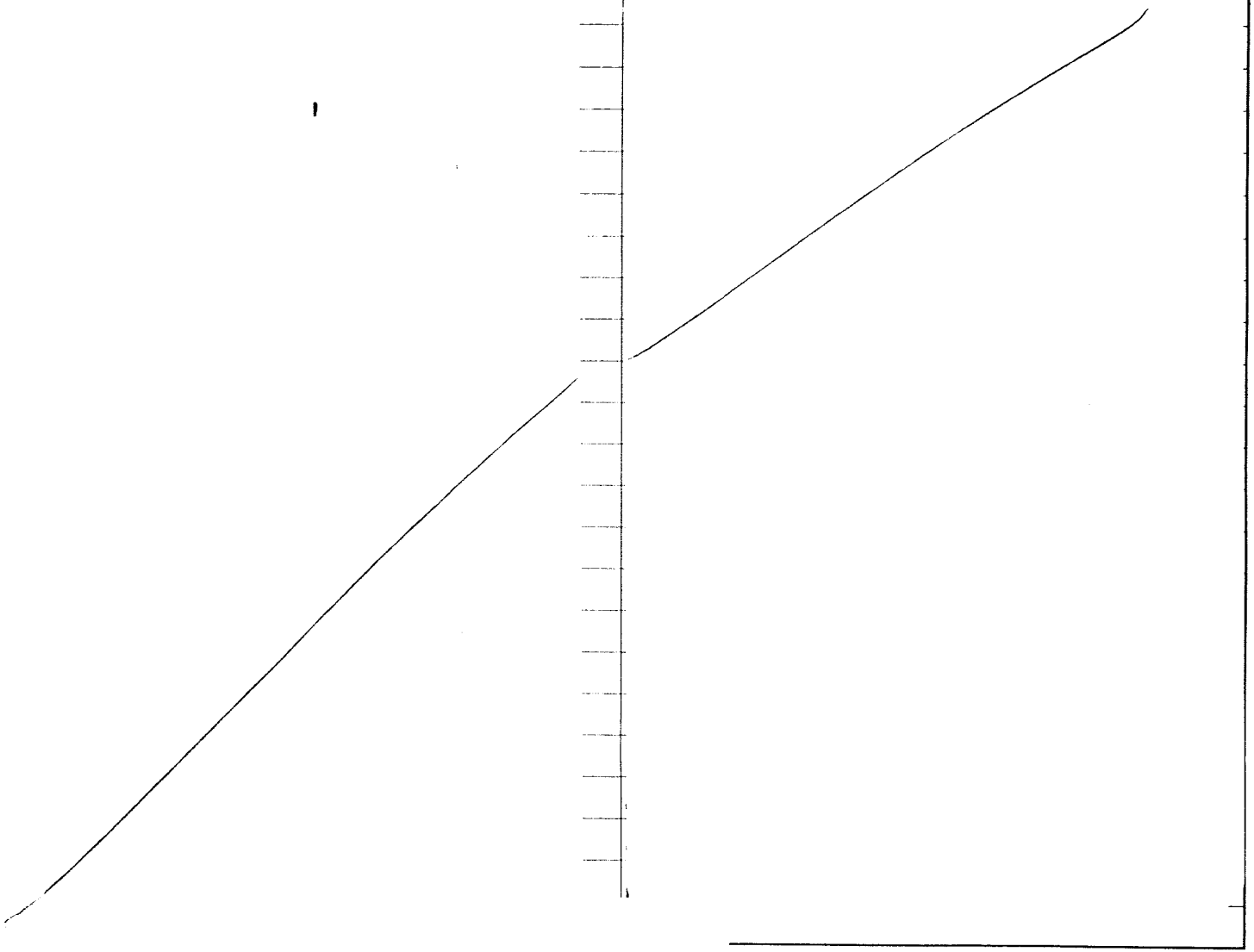


DRUG SCAN - 0224

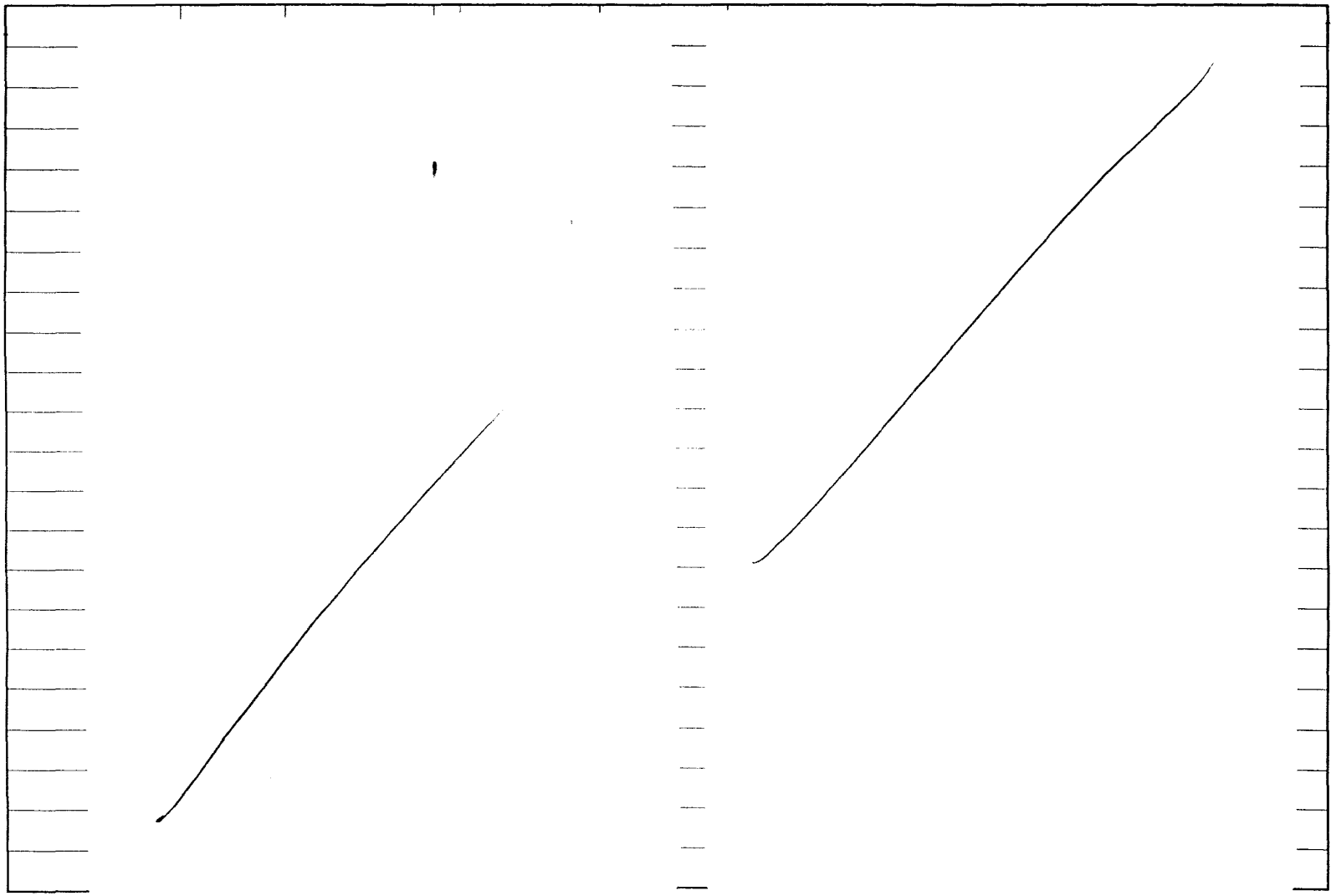


DRUG SCAN - 0224

SPECIMEN ID#	LAN	Date Received	Date Reported	Reported As	Quantitative Results



DRUG SCAN - 0224



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 21, 2000

0224
Dr. Richard D. Cohn
Dr. Mark R. Lichtenwalner
DrugScan, Inc.
1119 Mearns Road
P.O. Box 2969
Warminster, PA 18974

Dear Dr. Cohn and Dr. Lichtenwalner:

The enclosed critique was developed from the inspection report associated with the November 8-10, 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/svt224

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0224
Document No. Final

Laboratory: DrugScan, Inc.

Location: Warminster, PA

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 8 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

DRUGSCAN®

Medical and Forensic Toxicology Services

December 15, 2000

Dr. John Mitchell
National Laboratory Certification Program
Research Triangle Institute
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709-2194

RE: SVT 224 critique

Dear Dr. Mitchell:

We are in receipt of your letter dated November 21, 2000, outlining deficiencies noted during the November 8 – 10 special specimen validity testing inspection, and propose the following corrective actions, and where appropriate, revisions to the SOPM, highlighted in yellow marker.

1119 Mearns Road, P.O. Box 2969, Warminster, PA 18974-0097, Telephone (215) 674-9310

Mark Lichtenwalner, Ph.D.
Responsible Person

RESEARCH TRIANGLE INSTITUTE

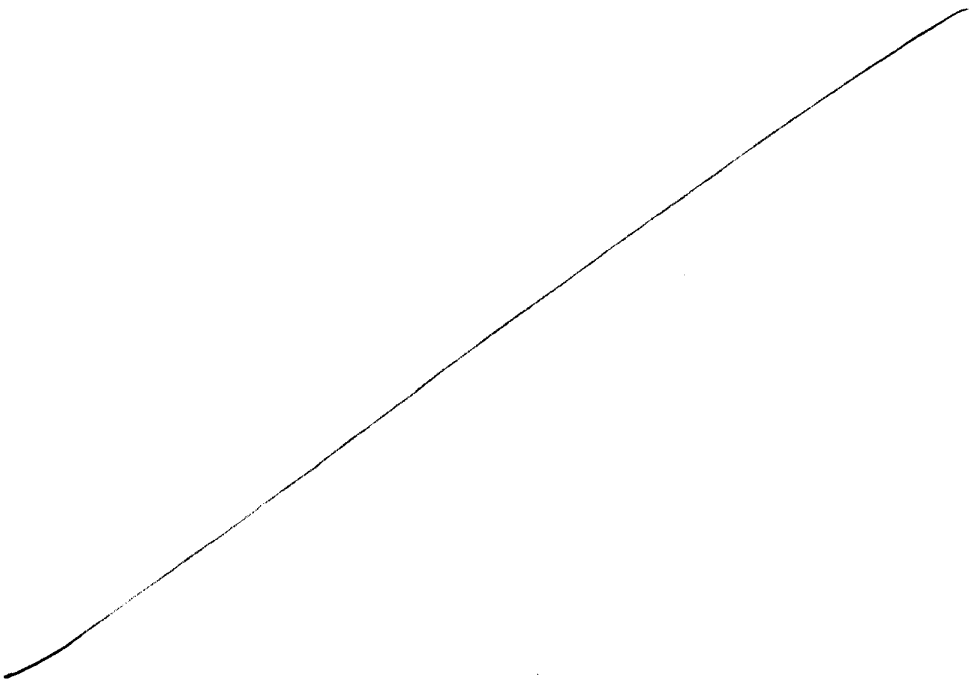
National Laboratory Certification Program

January 8, 2001

0224
Dr. Richard D. Cohn
Dr. Mark R. Lichtenwalner
DrugScan, Inc.
1119 Mearns Road
P.O. Box 2969
Warminster, PA 18974

Dear Dr. Cohn and Dr. Lichtenwalner:

We have reviewed the material provided in your correspondence of December 15, 2000, submitted in response to issues raised during the November 8-10, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 21, 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's 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. ***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/SVT0224