

Validity Testing Information Part I

Laboratory Name:

Lab ONE

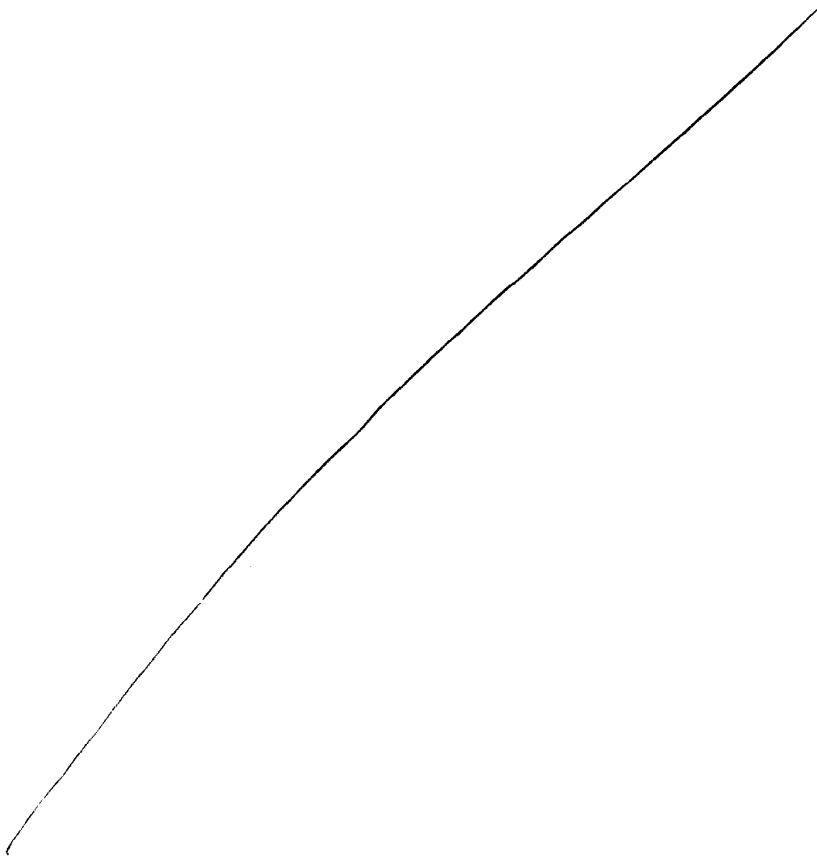
Address:

10101 Renner Blvd Lenexa, KS 66219

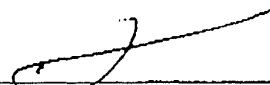
Responsible Person:

Michael Peat

(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

10-5-00

Date

MICHAEL A. PEAT

Printed Name, Responsible Person

ATTACHMENT

NLCP PD 37

fu.
10.5.00

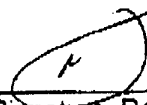
Validity Testing Information Part II

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).



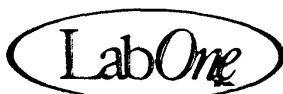
Signature, Responsible Person

10-18-00

Date

MICHAEL A. PEAT

Printed Name, Responsible Person



MICHAEL A. PEAT, Ph.D.

President, Substance Abuse Testing Division and Executive Vice President, Toxicology

MEMO: FROM MICHAEL A. PEAT PH.D.

DATE: OCTOBER 17, 2000
TO: KEN DAVIS, RTI
CC: LANCE PRESLEY, DAWN HAHN
FROM: MIKE PEAT
RE: AUDIT REQUEST FOR SUBSTITUTED AND ADULTERATED SPECIMENS

Please find attached three spreadsheets for the data requested.

The data included in the attached spreadsheets were retrieved in the following manner:

In conversations with Drs Mitchell and Baylor and you, we discussed the retrieval of these data for the upcoming inspection. We will immediately begin pulling data for the substituted specimens and await instructions regarding the adulterated ones.

Thank you for your patience and understanding in this matter.

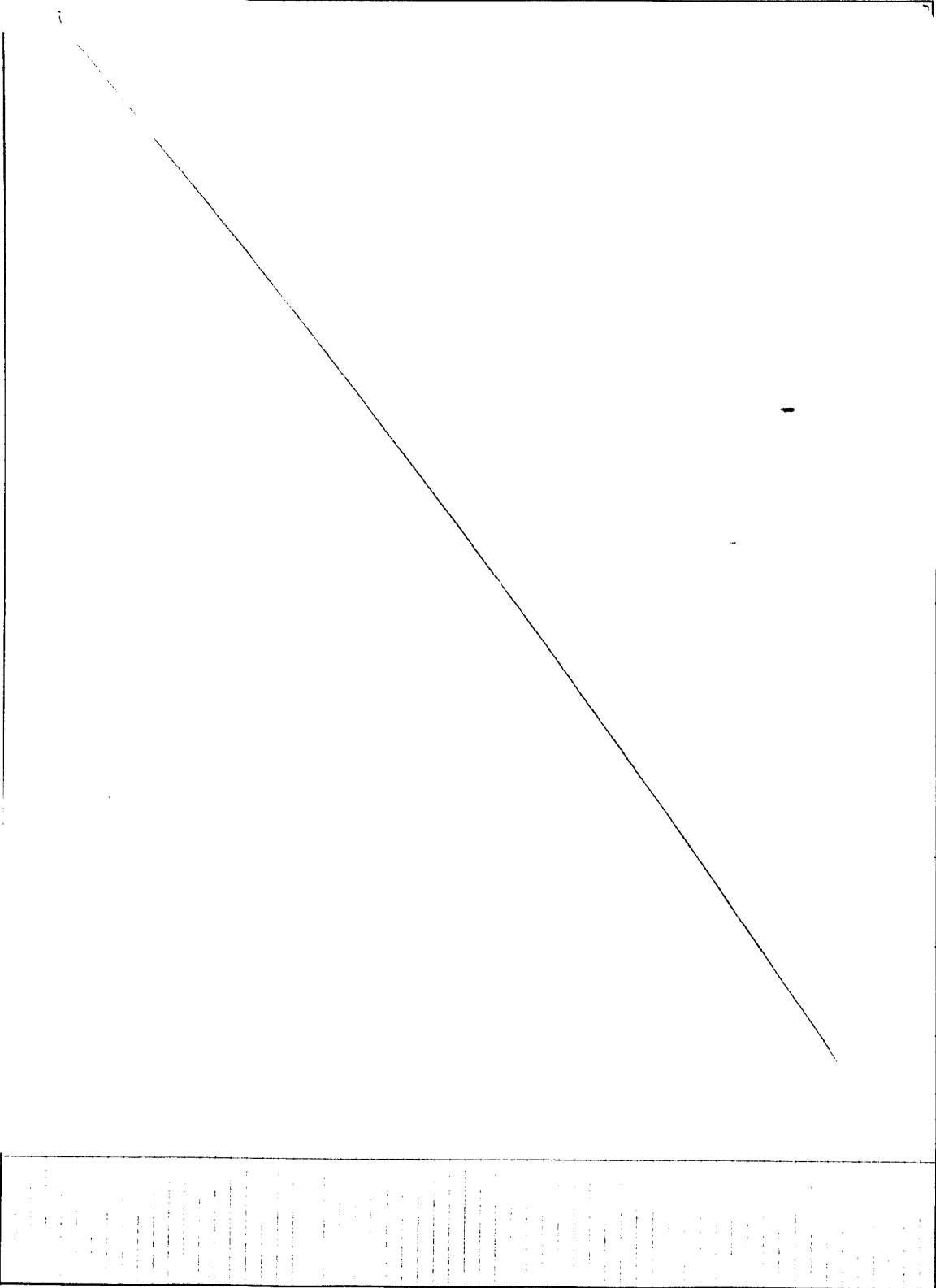
MAP

Confidential

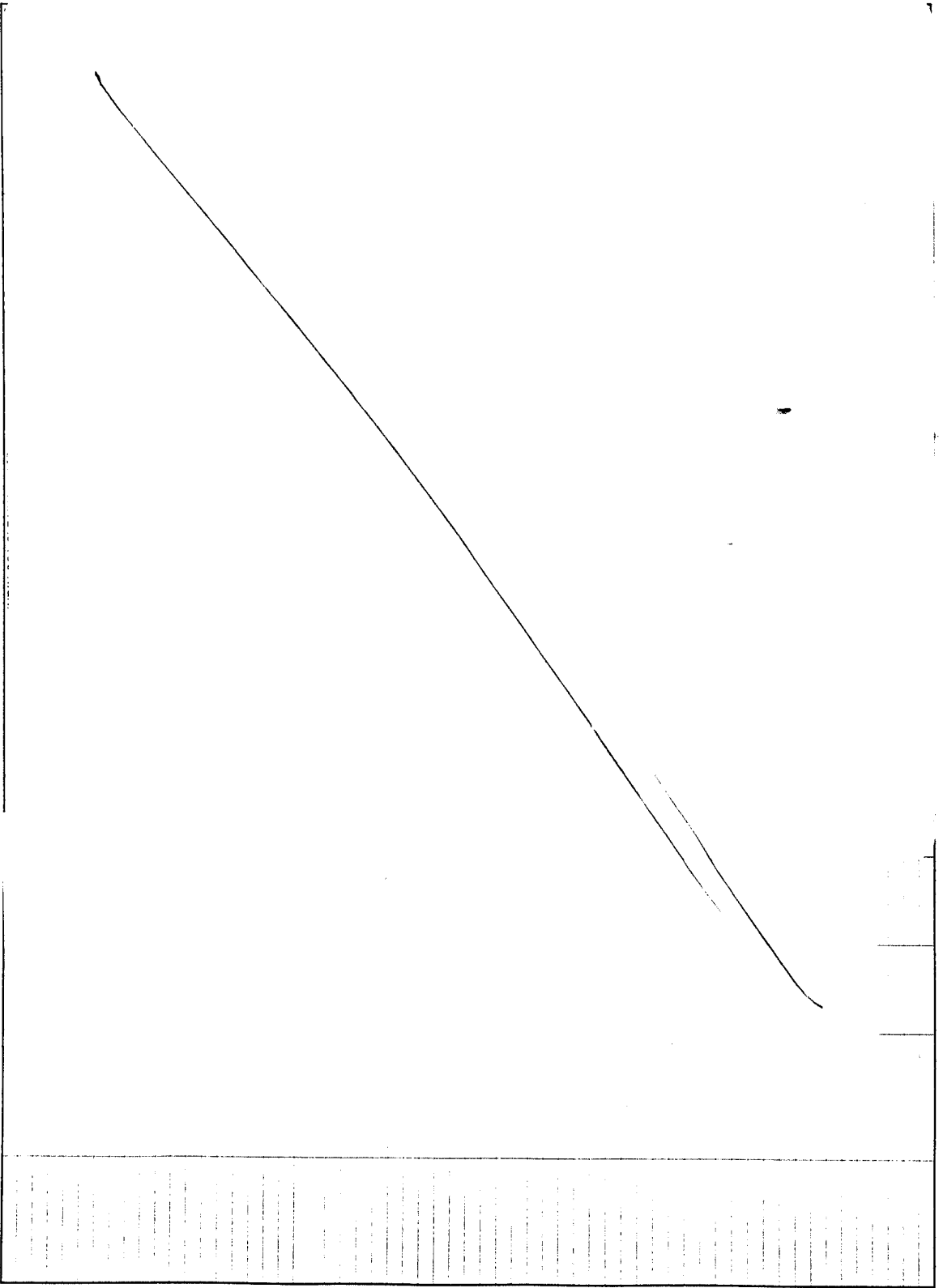
TOTAL SPECIMENS

COG#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

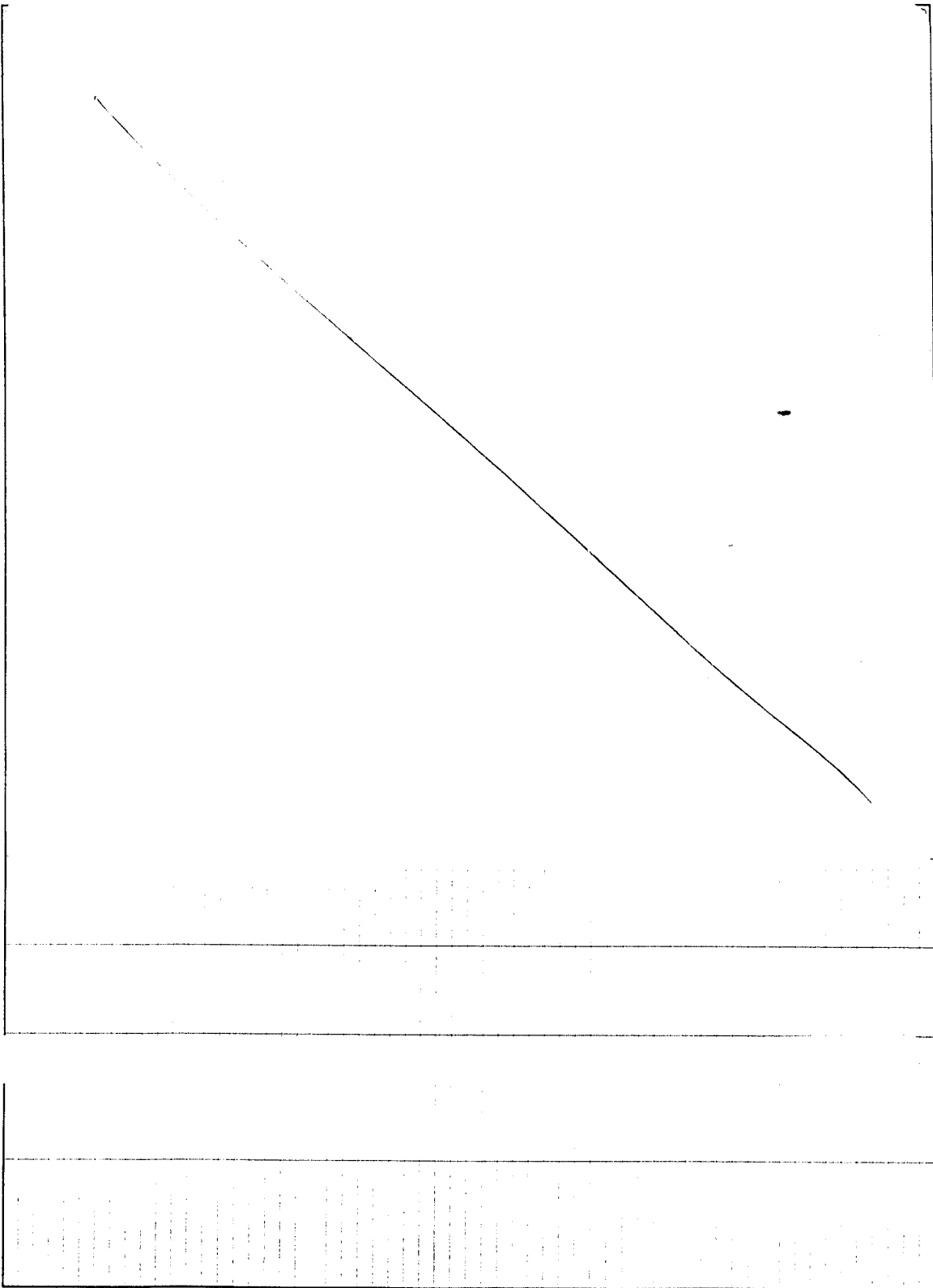
TOTAL SPECIMENS



TOTAL SPECIMENS

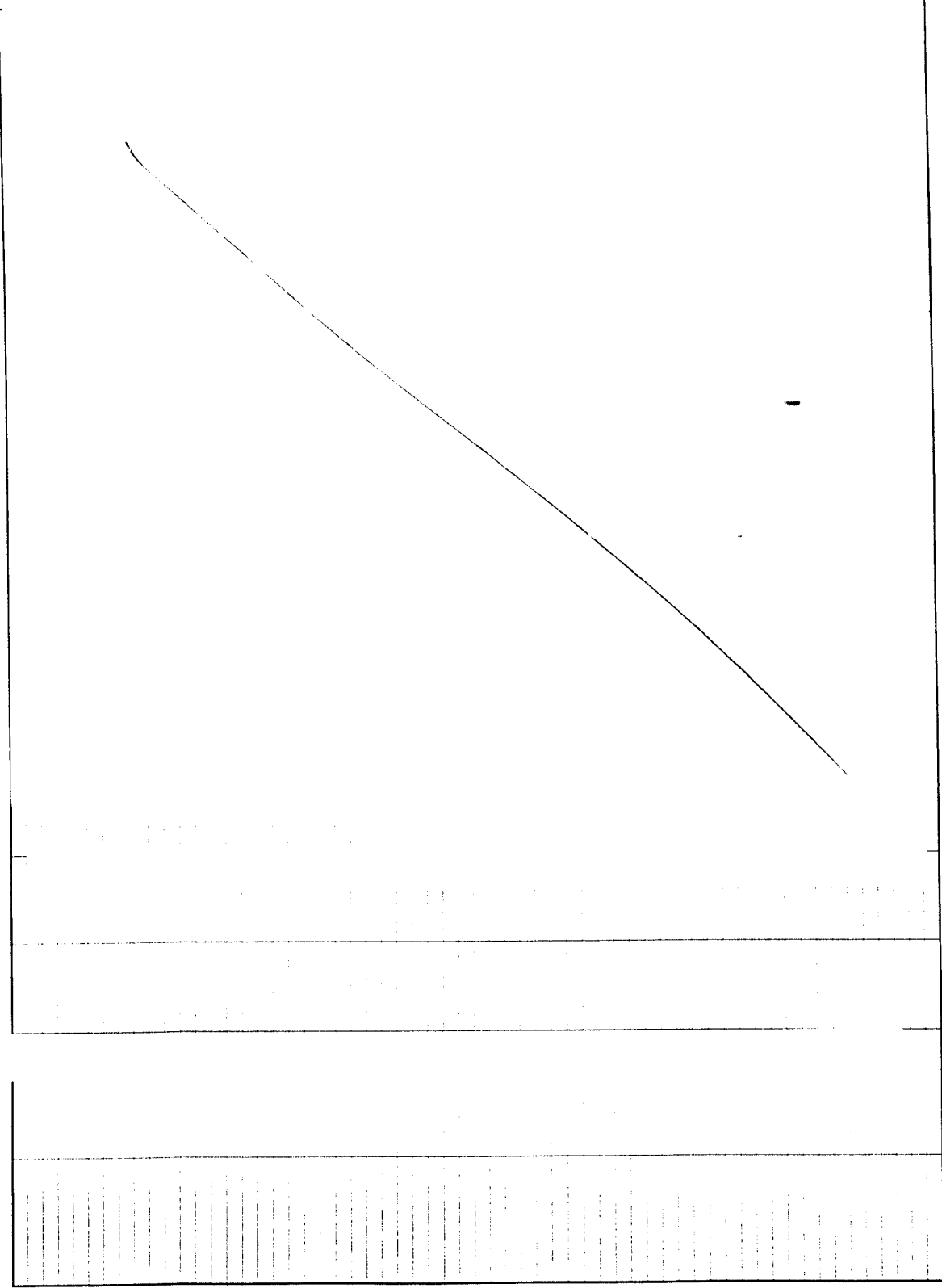


TOTAL SPECIMENS



Specimen ID	Quantity	Notes
[Redacted Content]		

TOTAL SPECIMENS



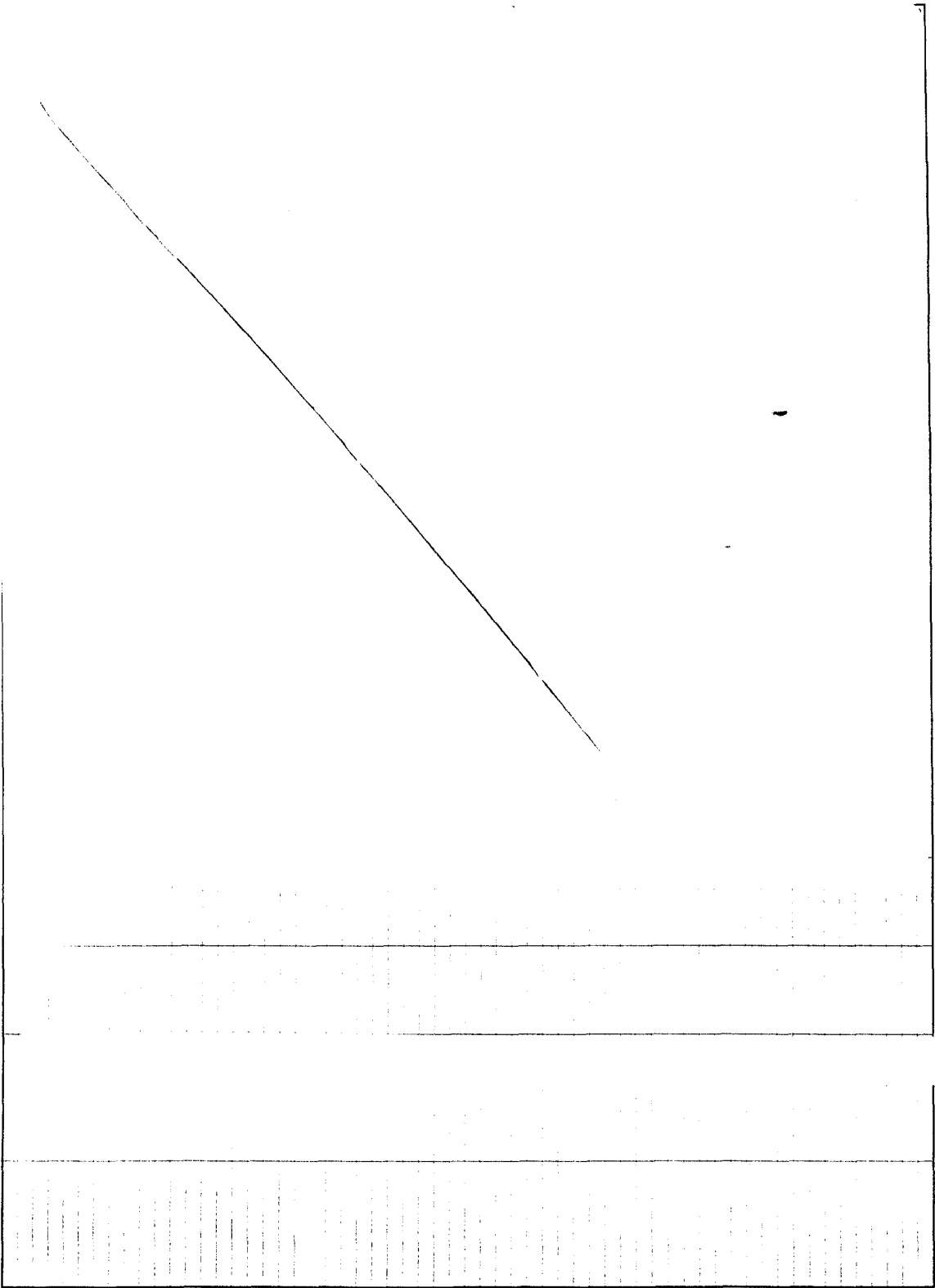
TOTAL SPECIMENS

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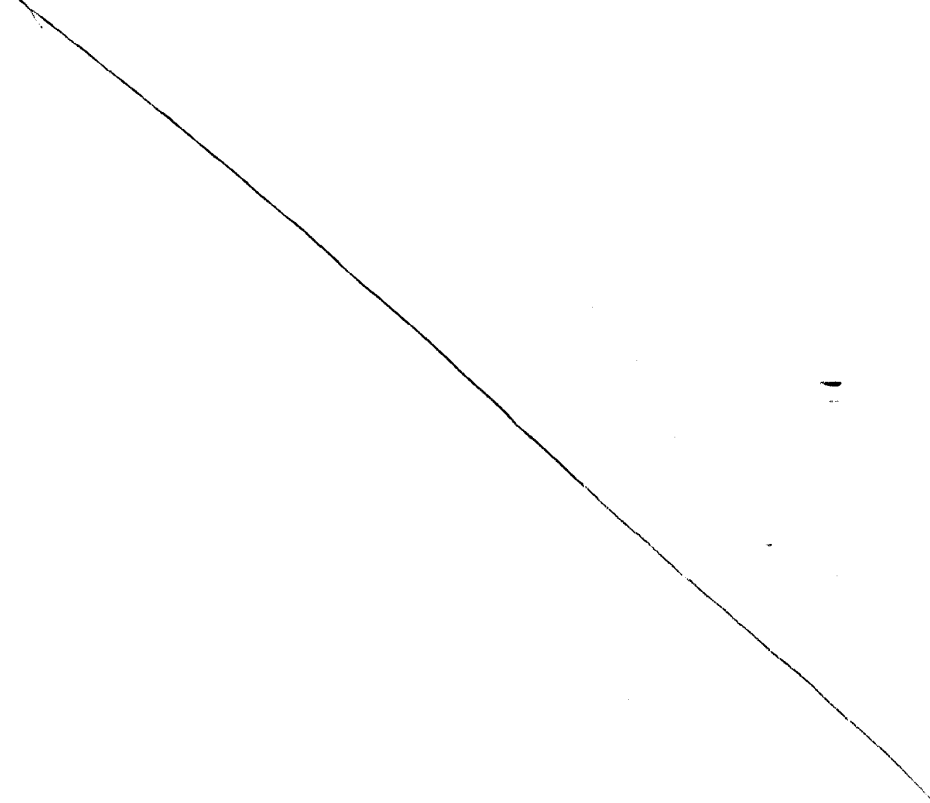
TOTAL SPECIMENS

Specimen No.	Specimen Description	Quantity	Total Specimens
1
2
3
4
5
6
7
8
9
10
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12
13
14
15
16
17
18
19
20
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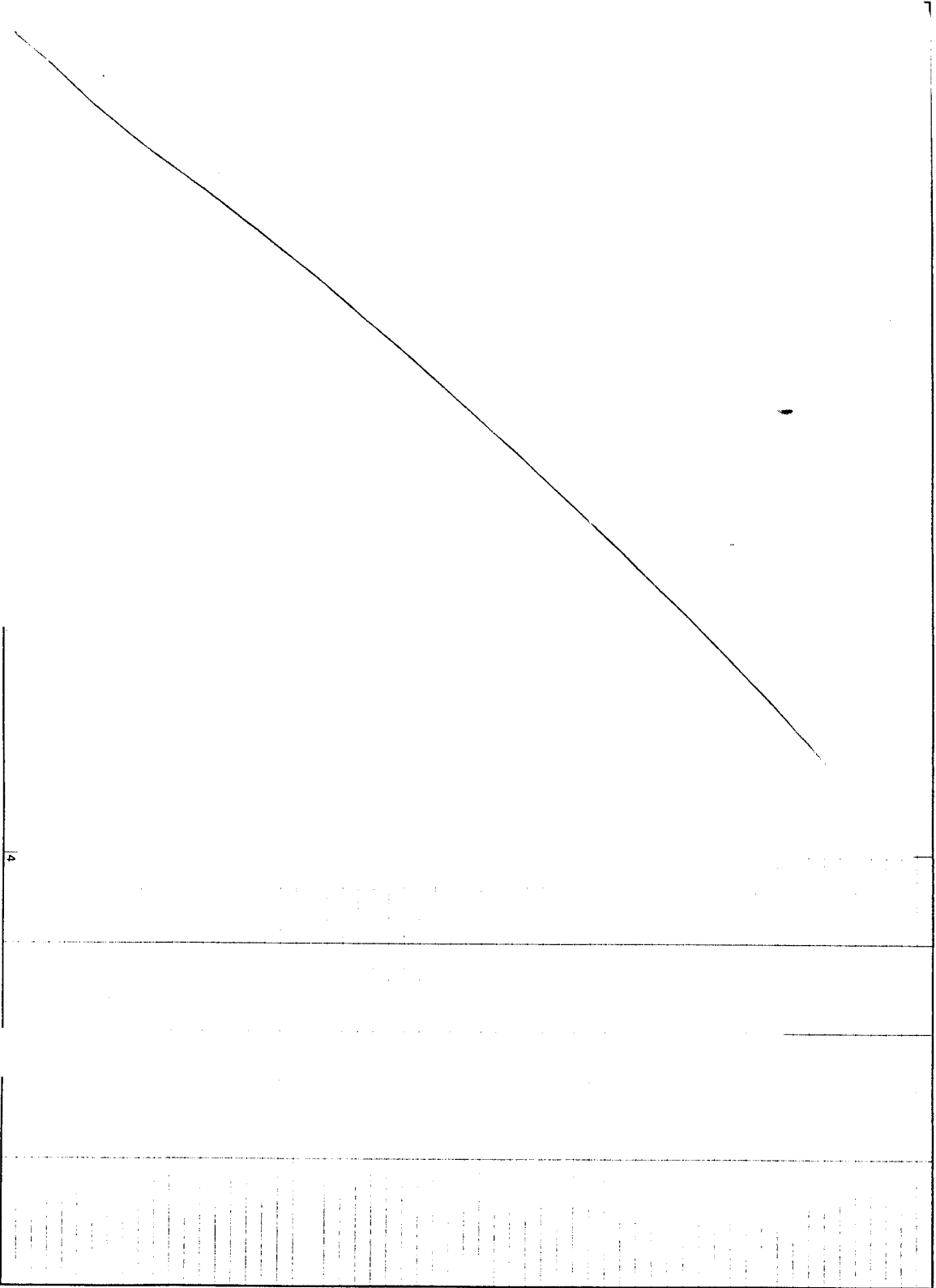
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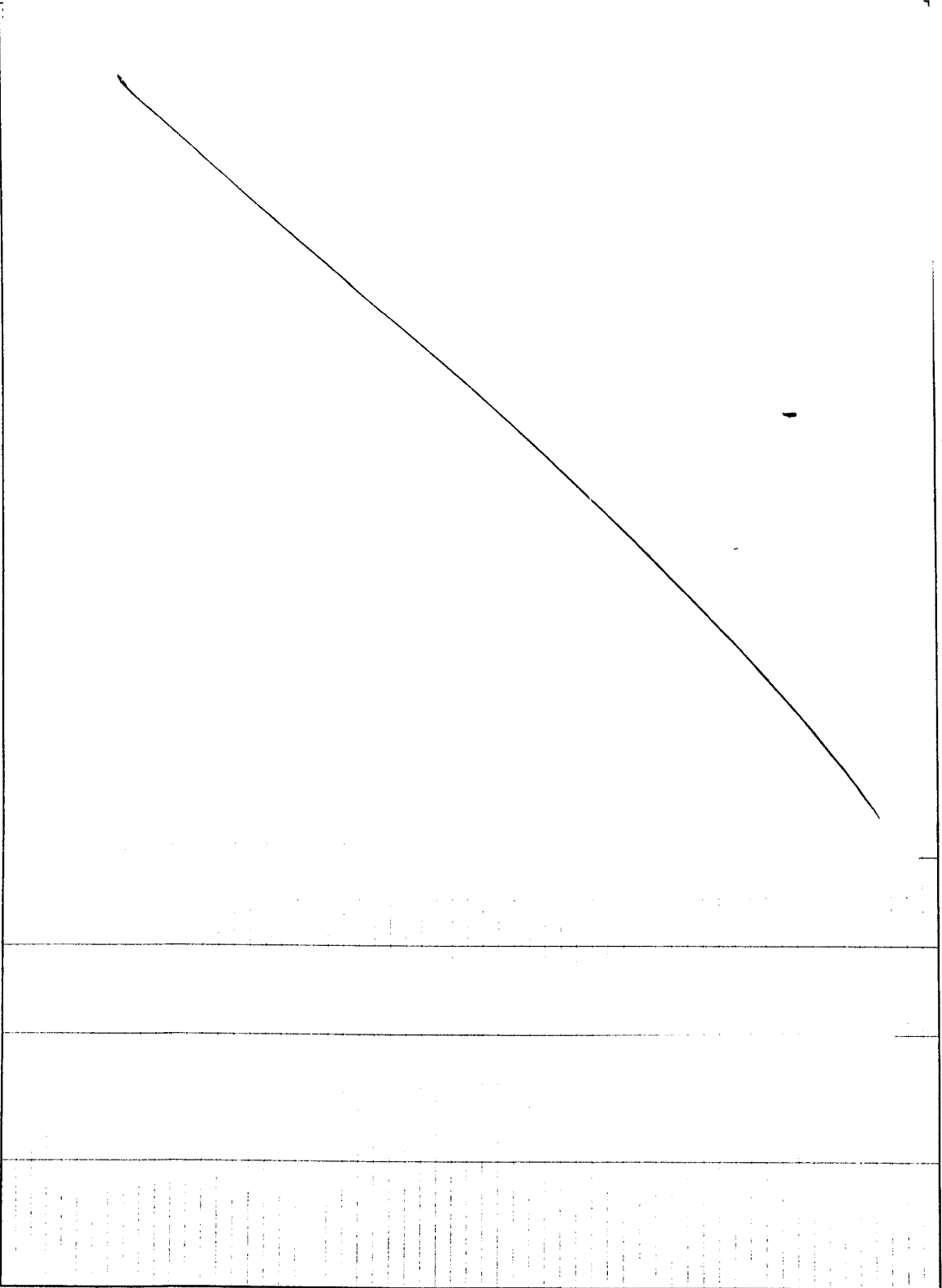
TOTAL SPECIMENS



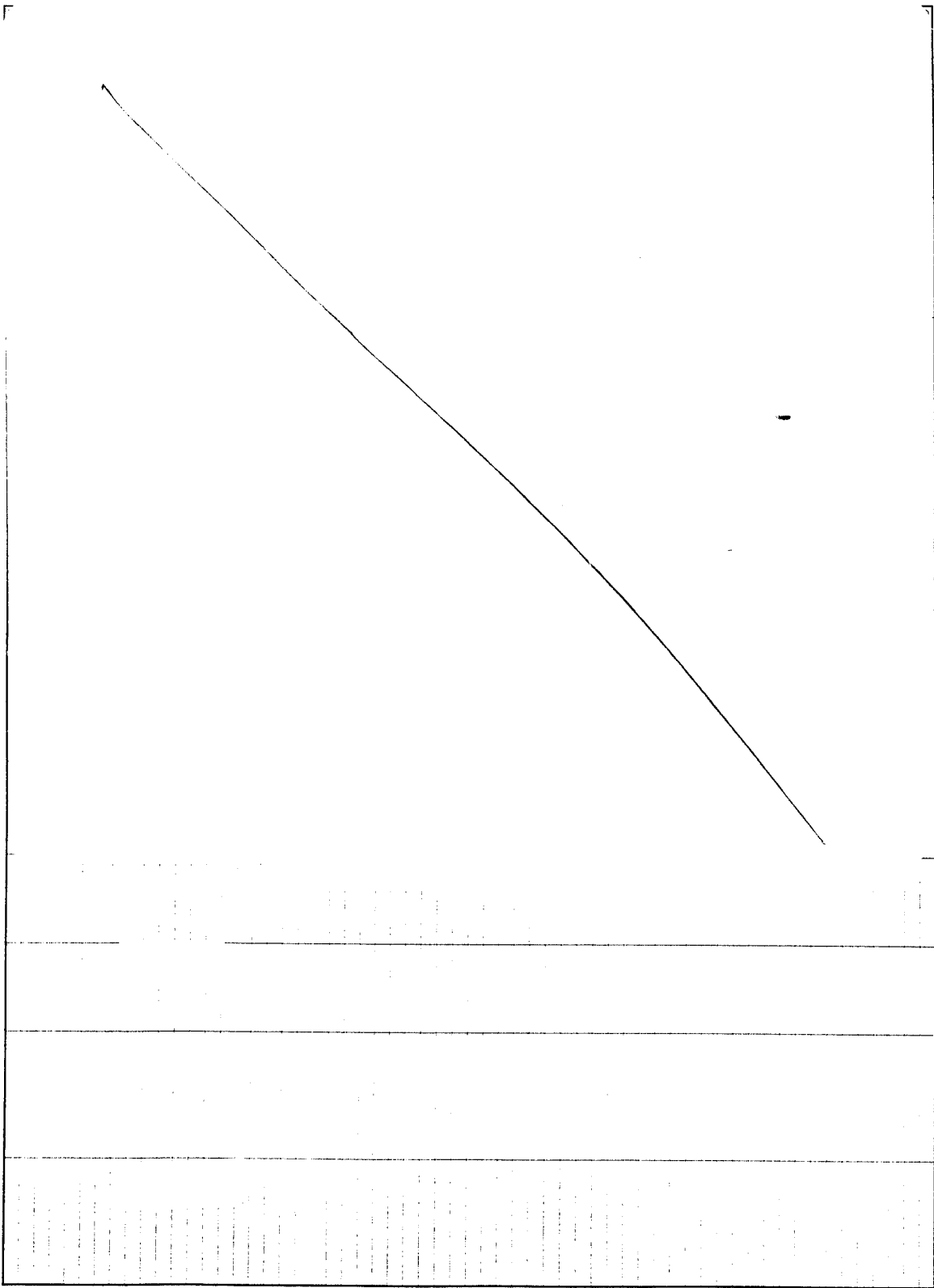
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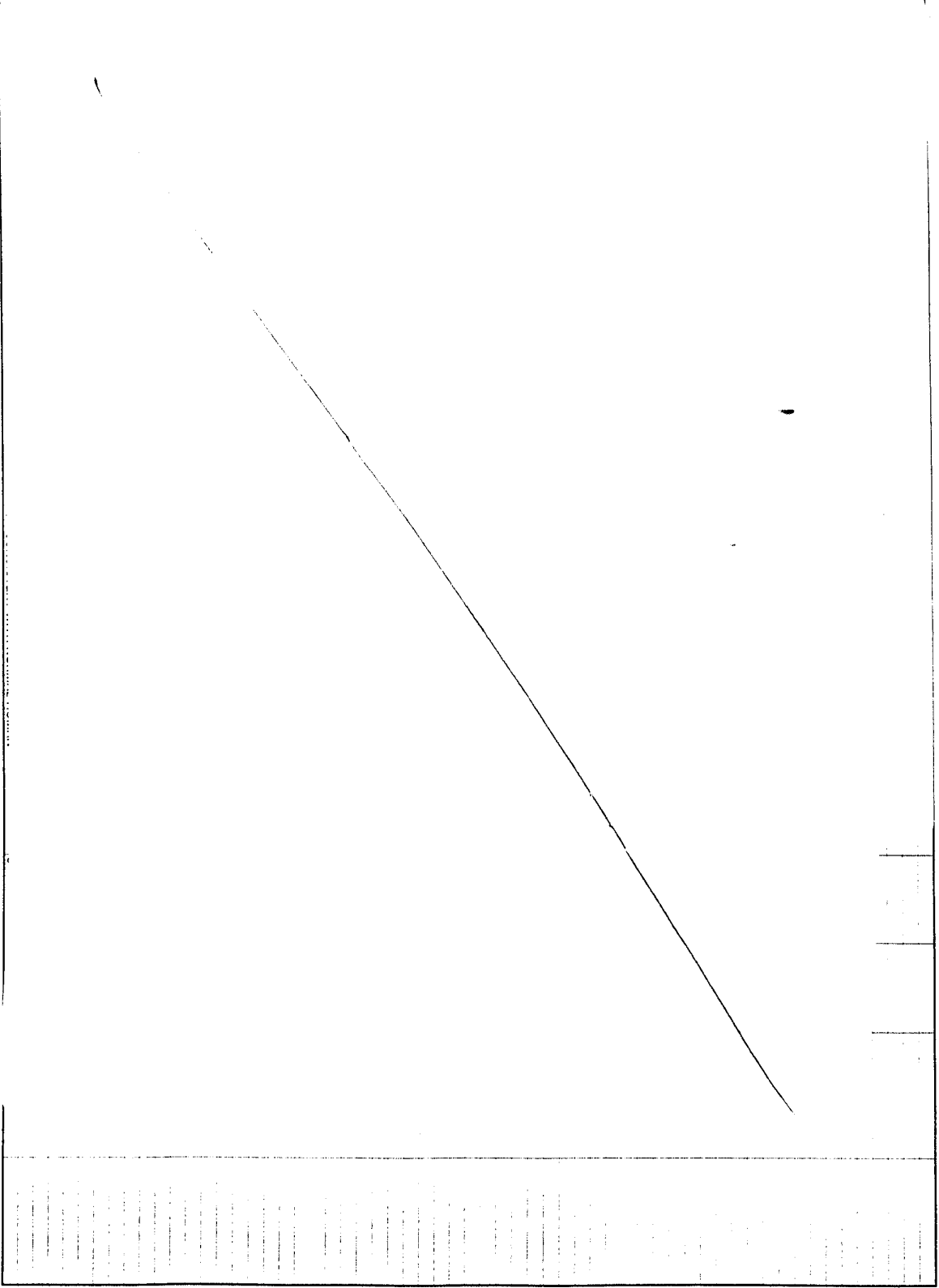
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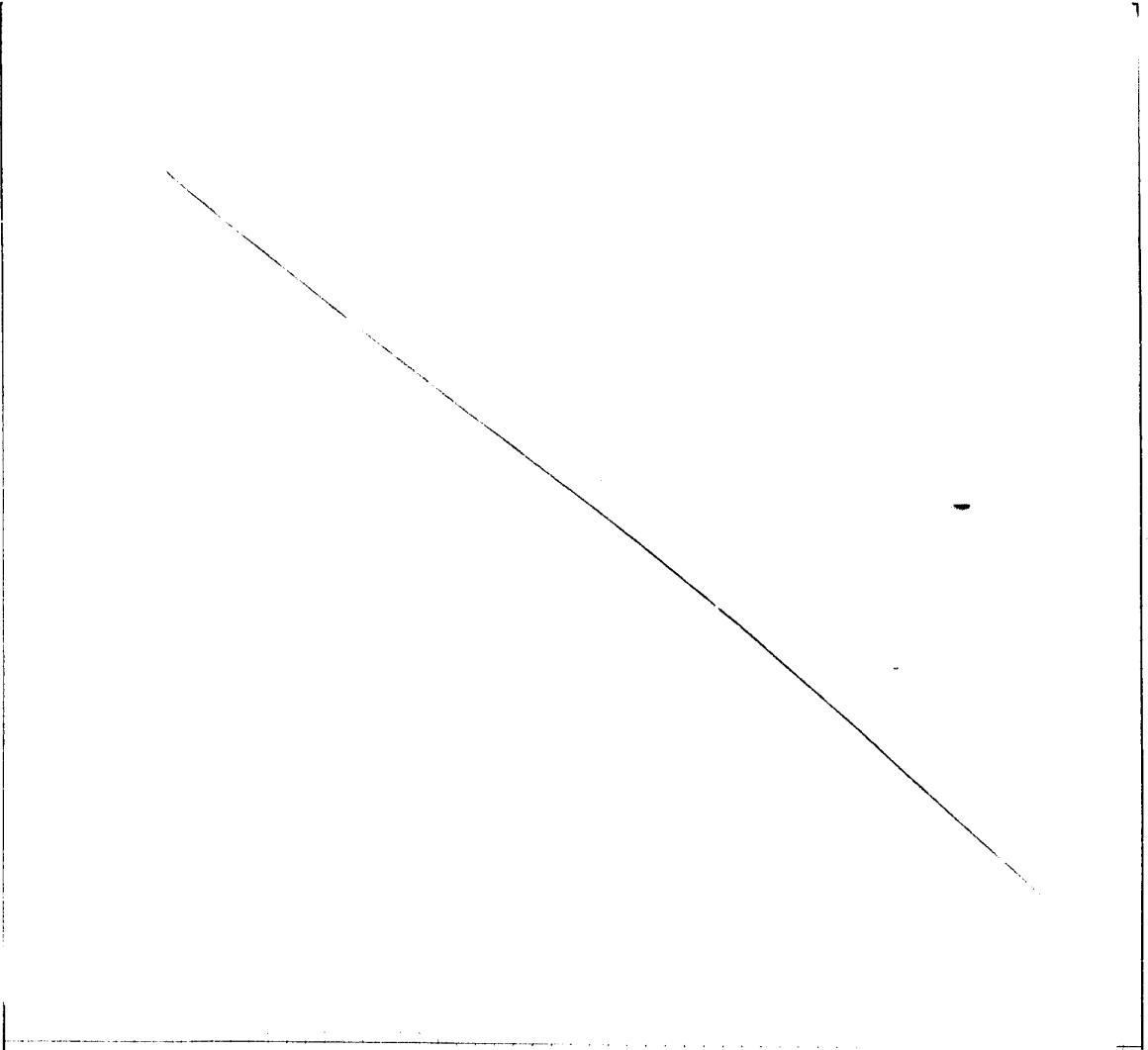
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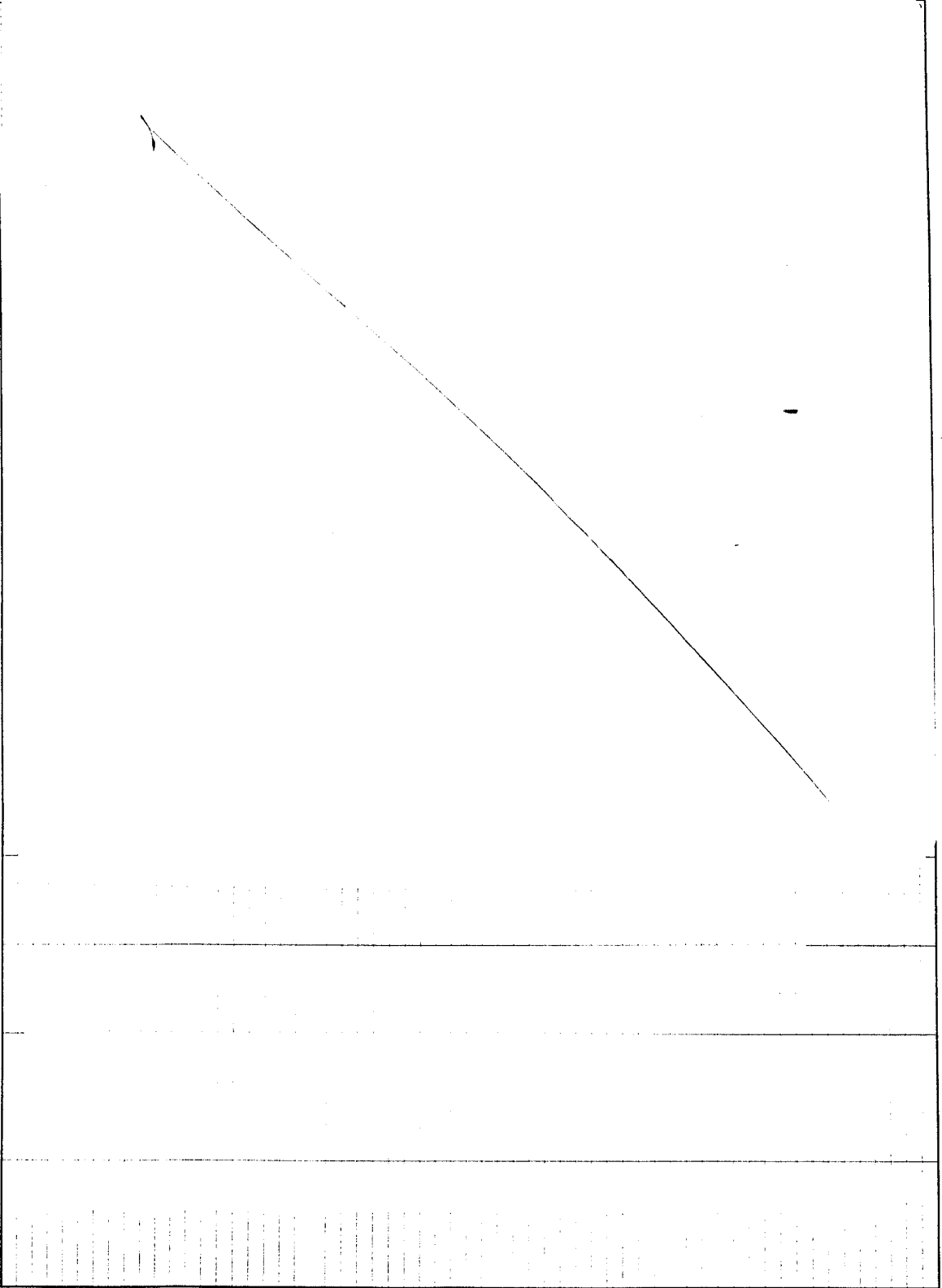
TOTAL SPECIMENS



TOTAL SPECIMENS

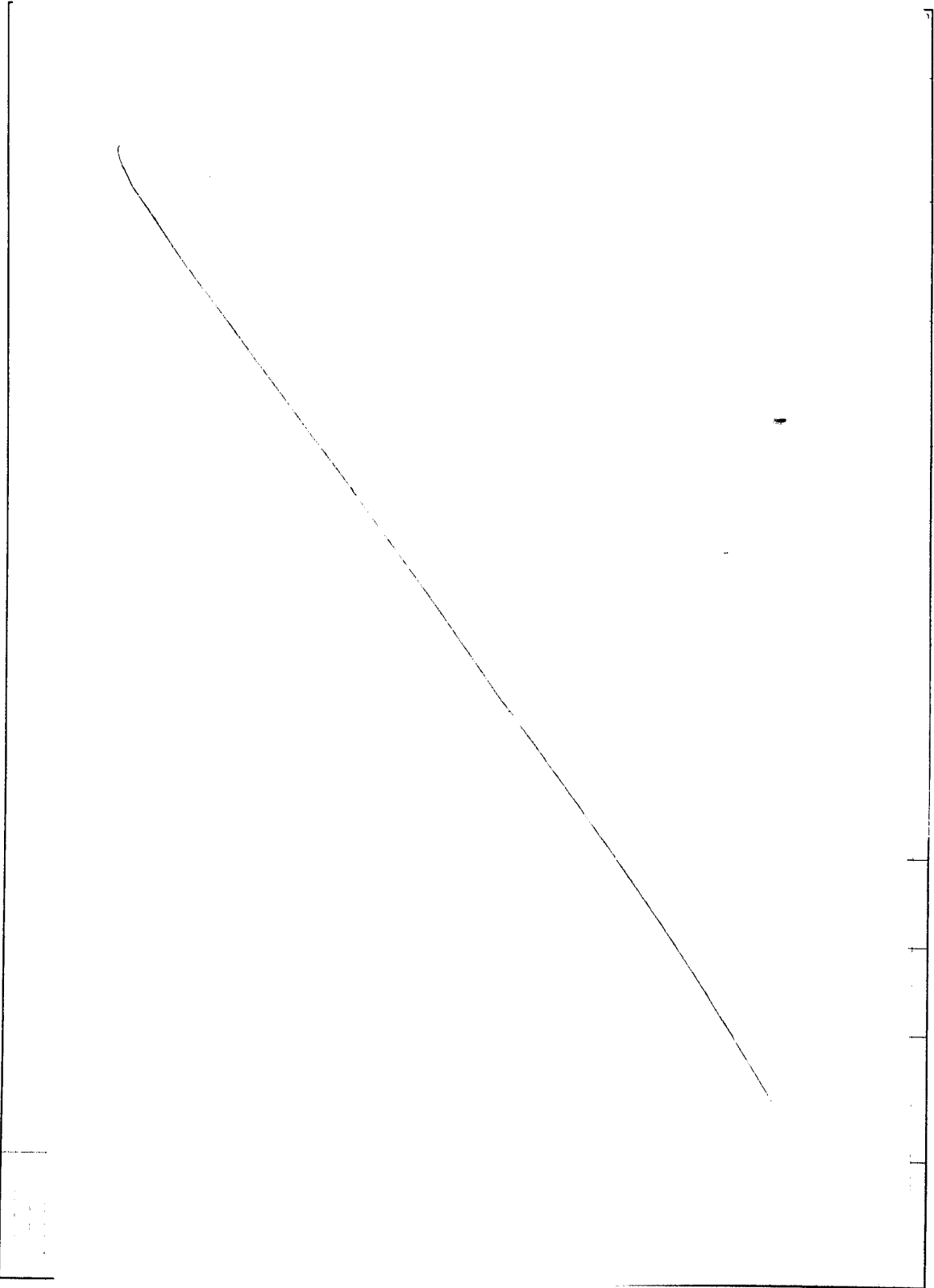
					
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TOTAL SPECIMENS

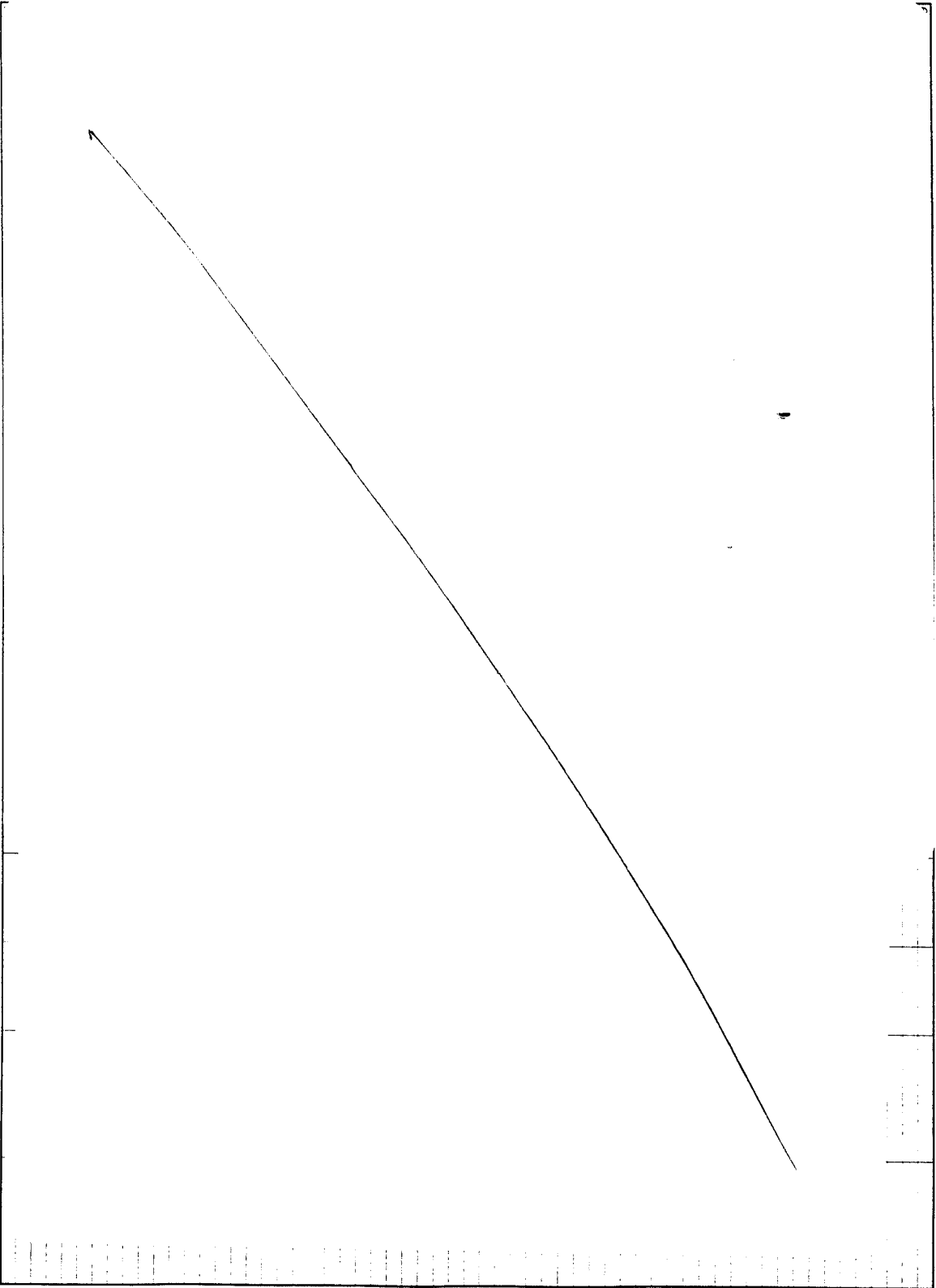


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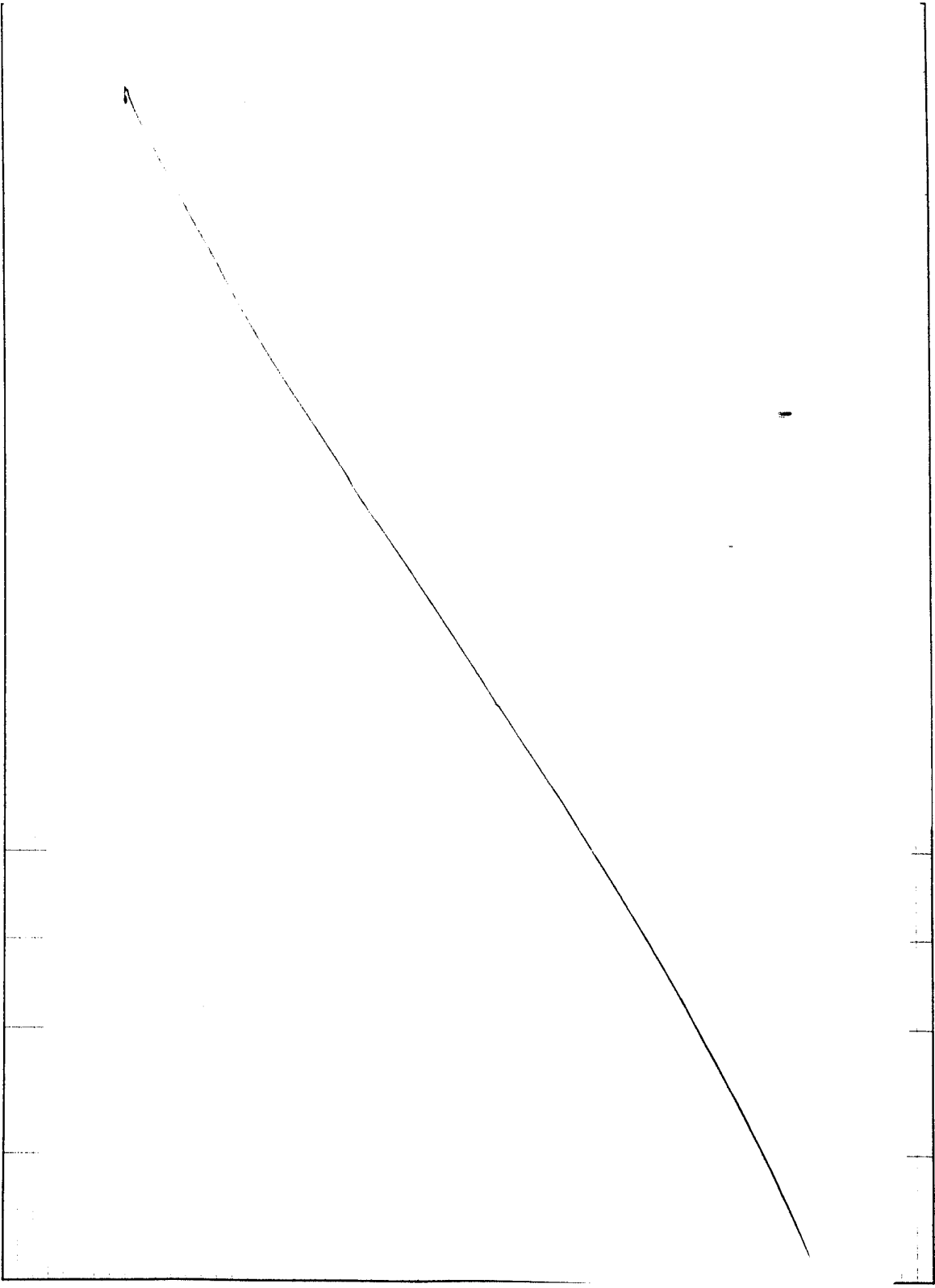
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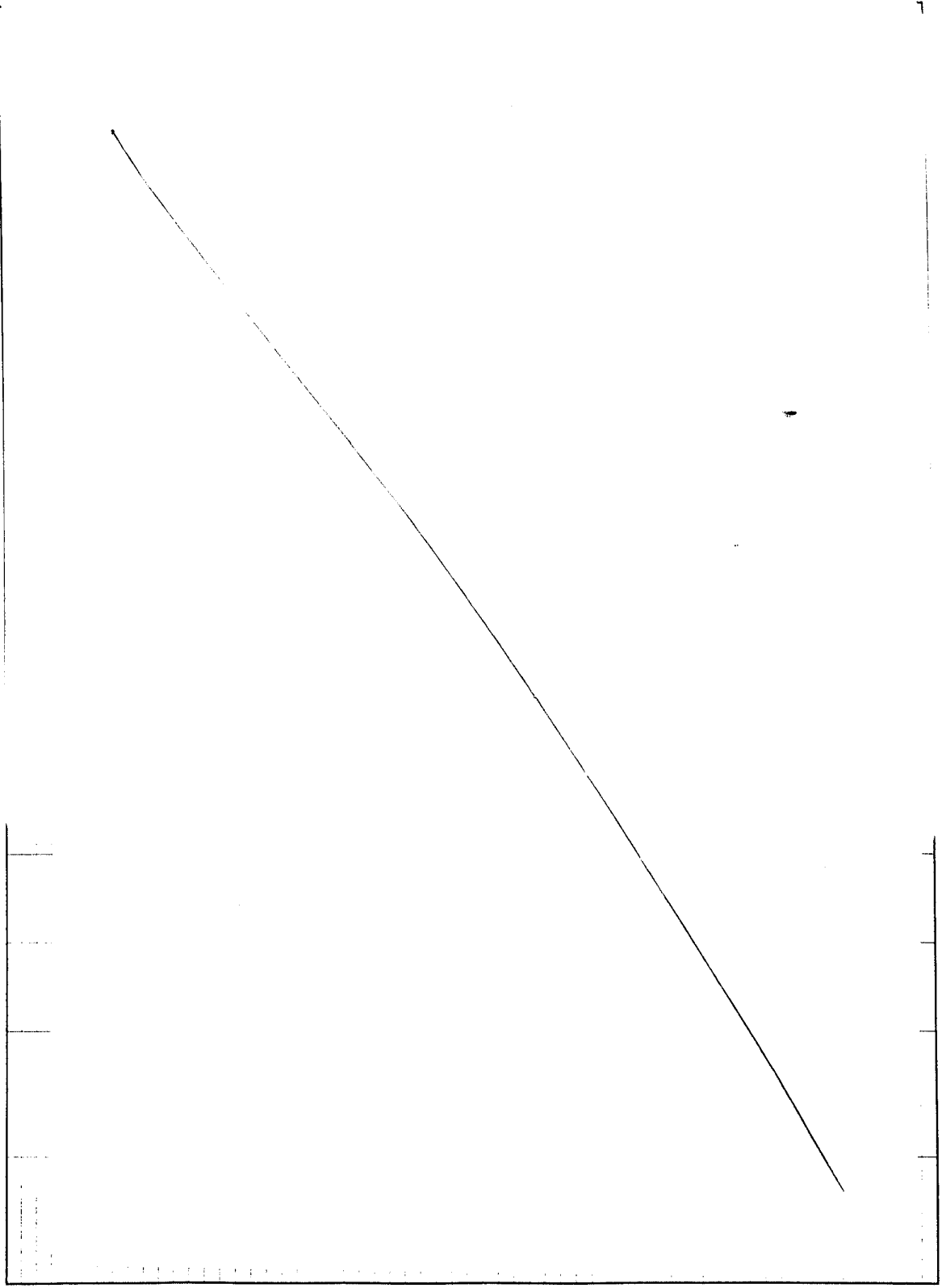
TOTAL SPECIMENS



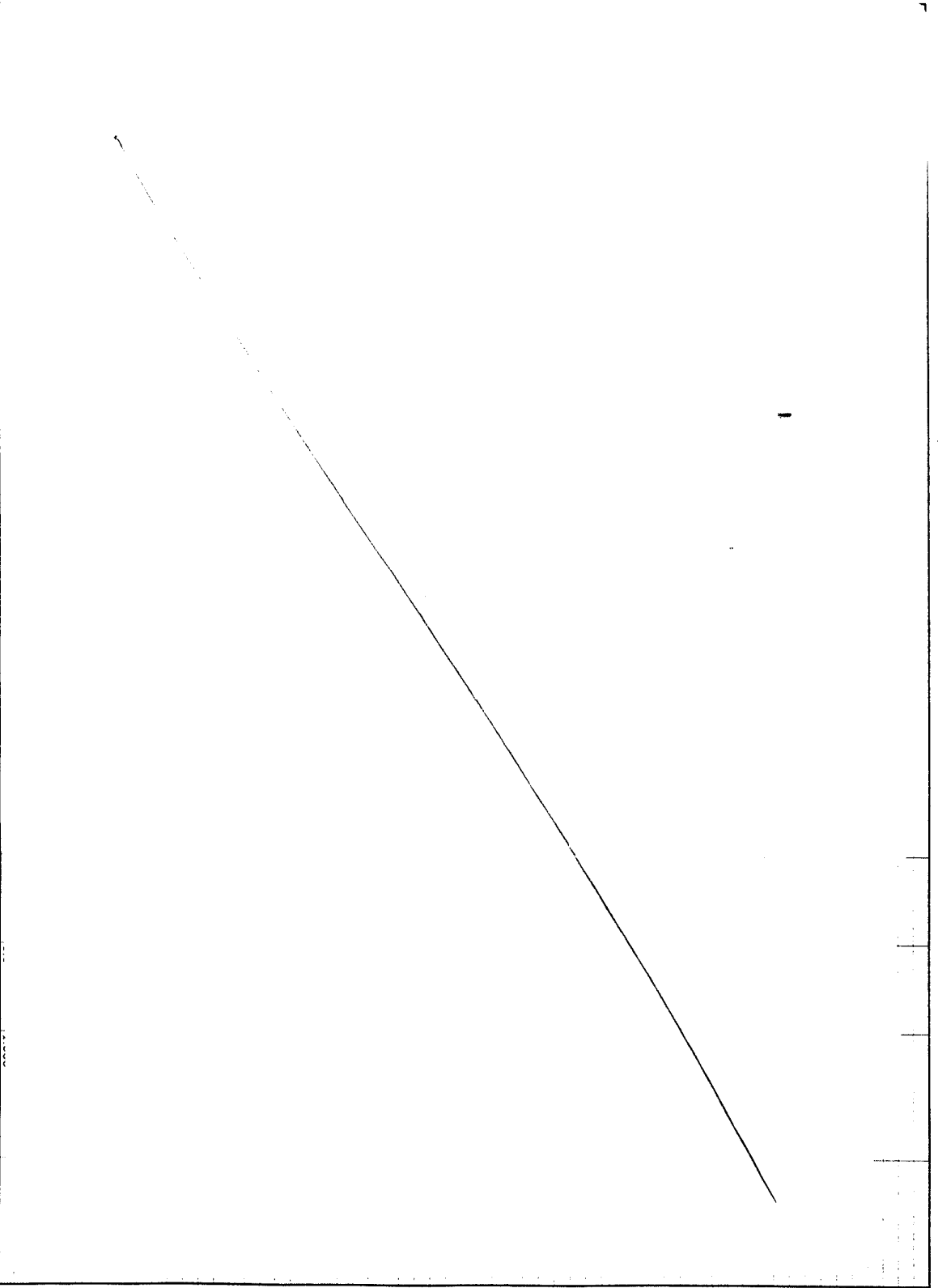
TOTAL SPECIMENS



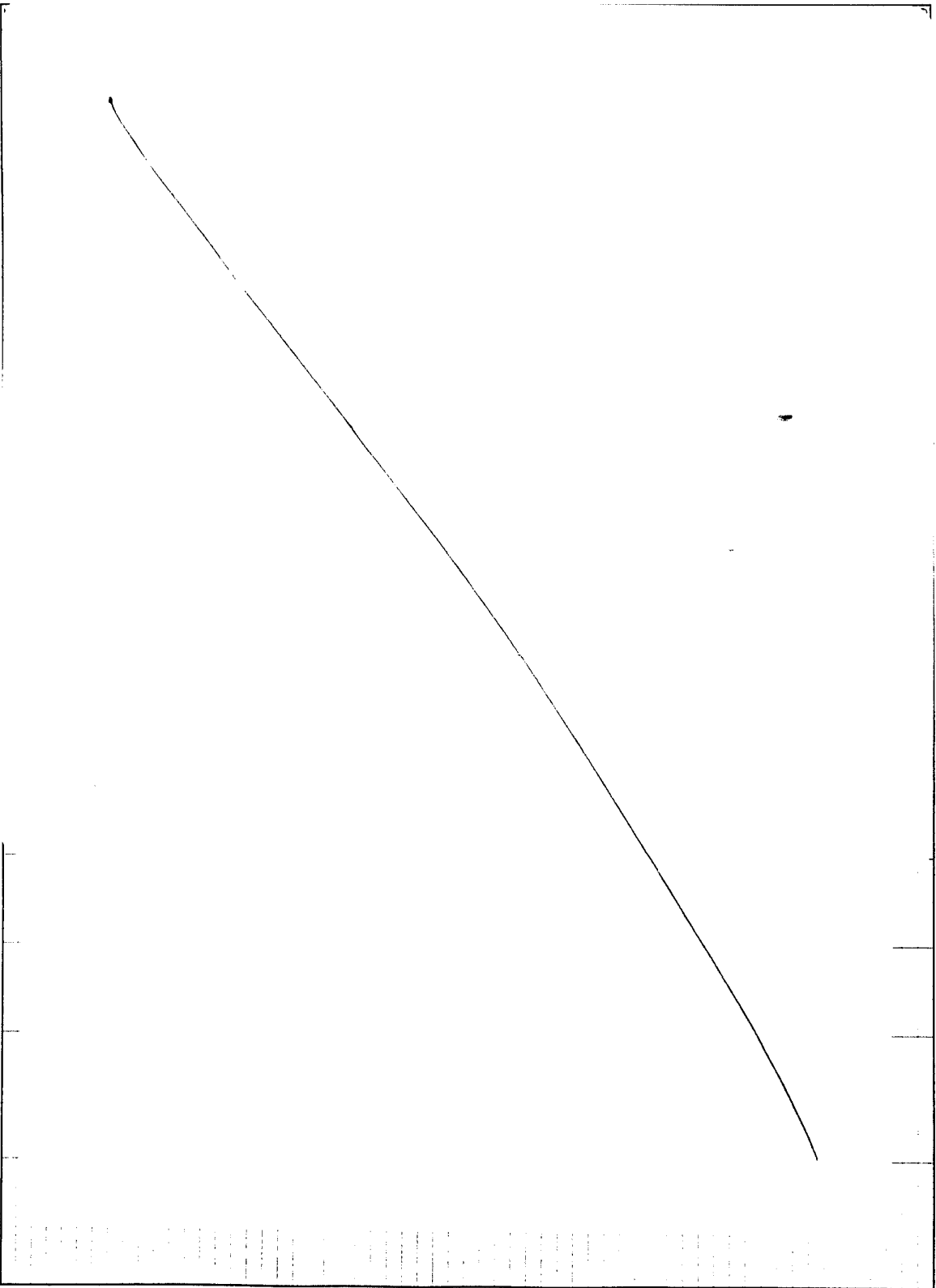
TOTAL SPECIMENS



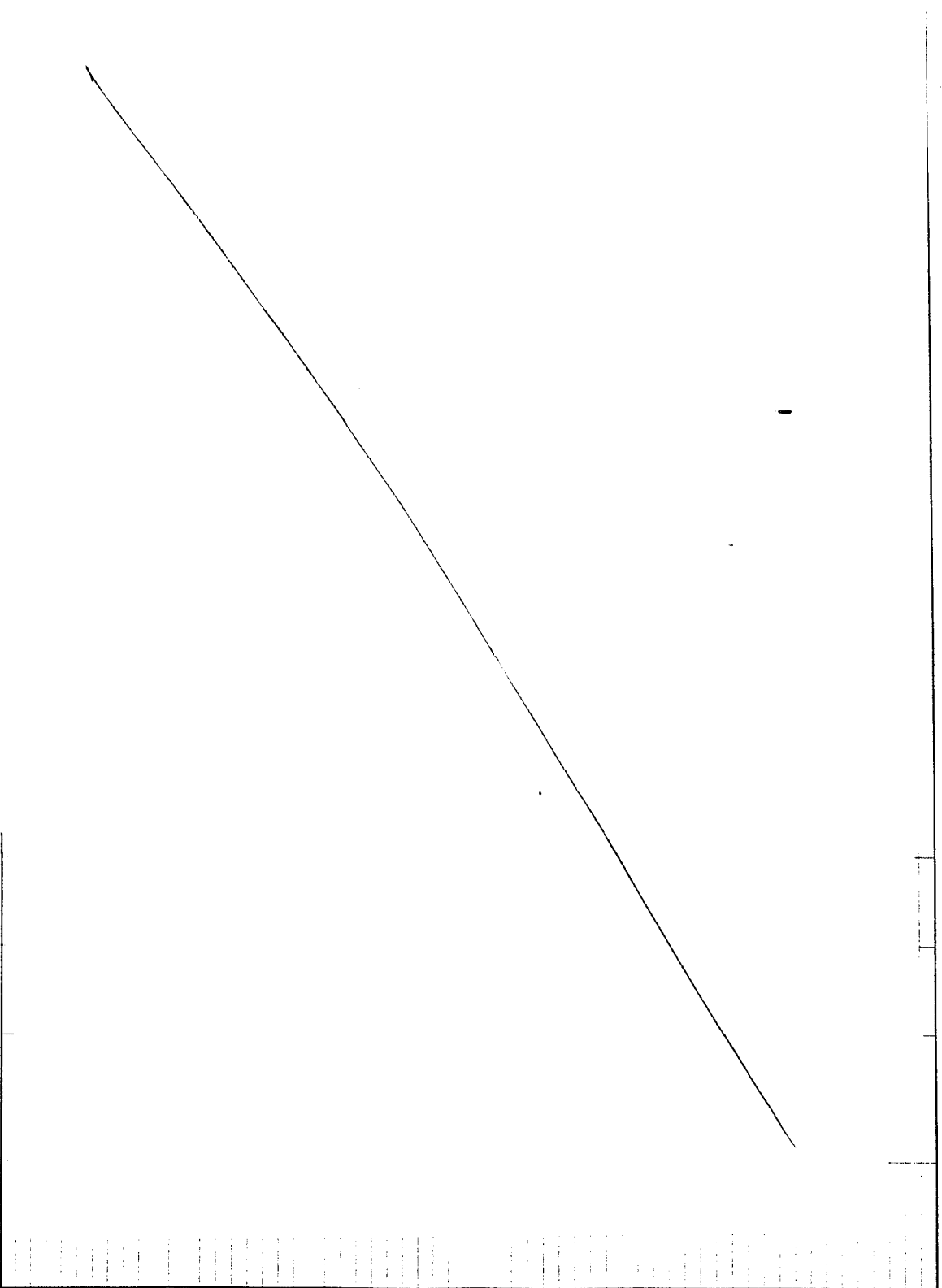
TOTAL SPECIMENS



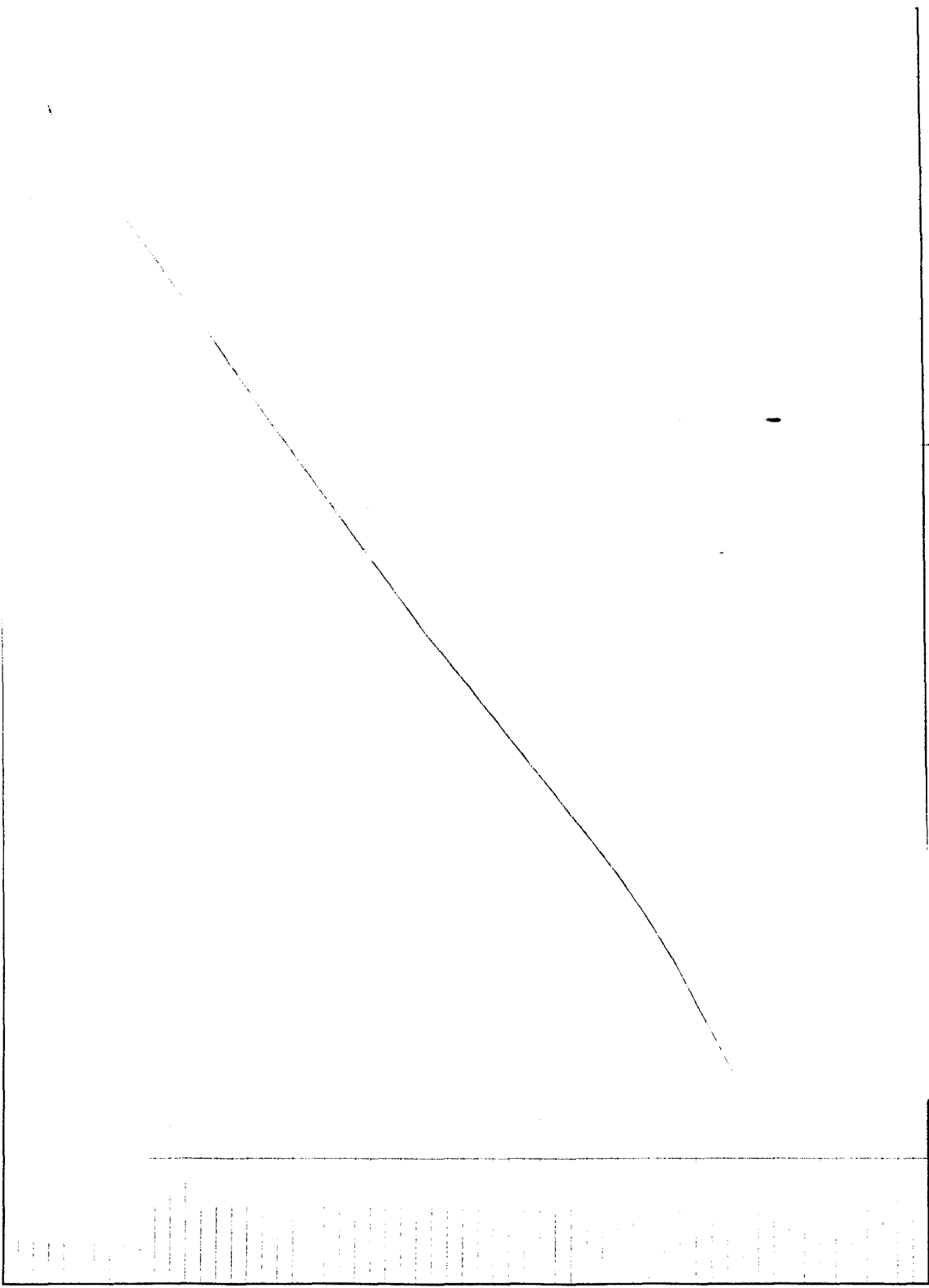
TOTAL SPECIMENS



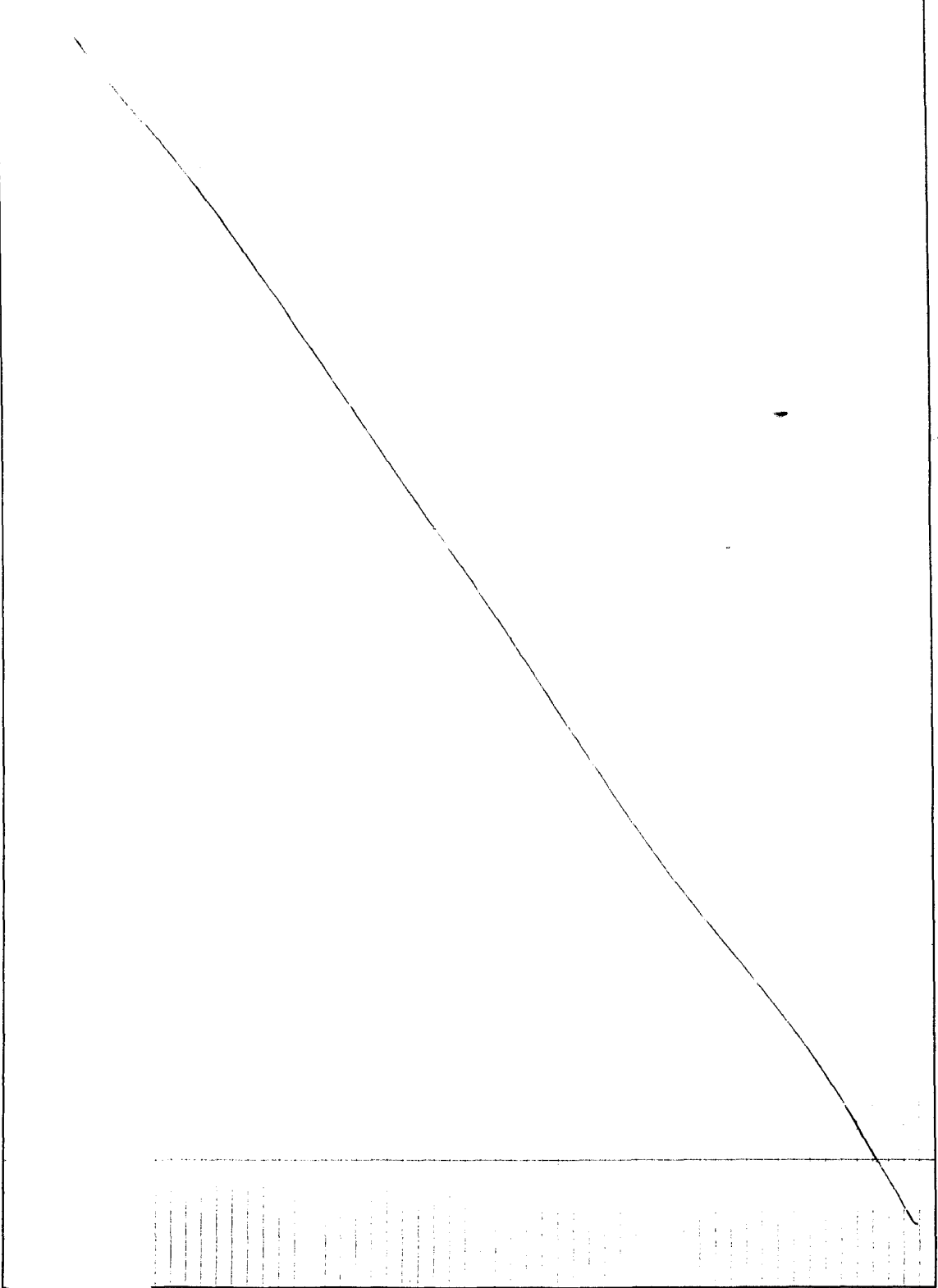
TOTAL SPECIMENS



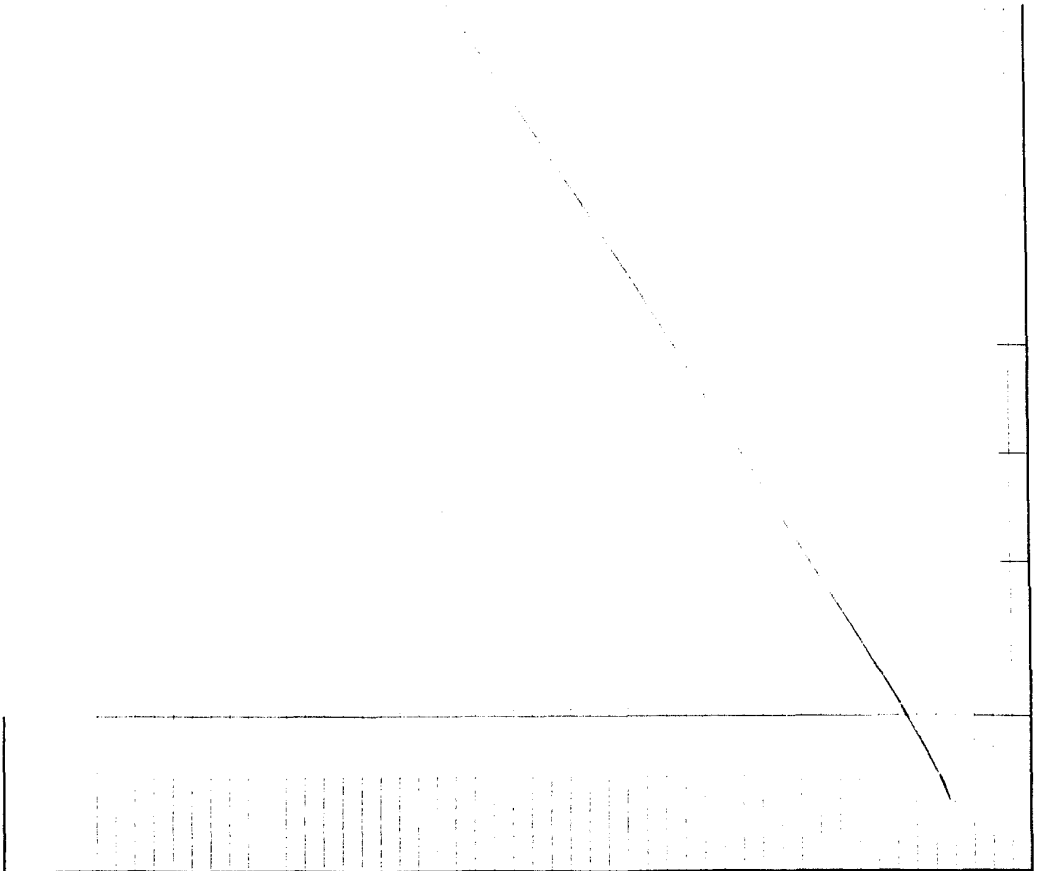
TOTAL SPECIMENS



TOTAL SPECIMENS



TOTAL SPECIMENS



ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
[A large diagonal line is drawn across the table, indicating that the data is illegible or redacted.]							

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
/							

ADULTERATED SPECIMENS

COCC #	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
/							

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
/							

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

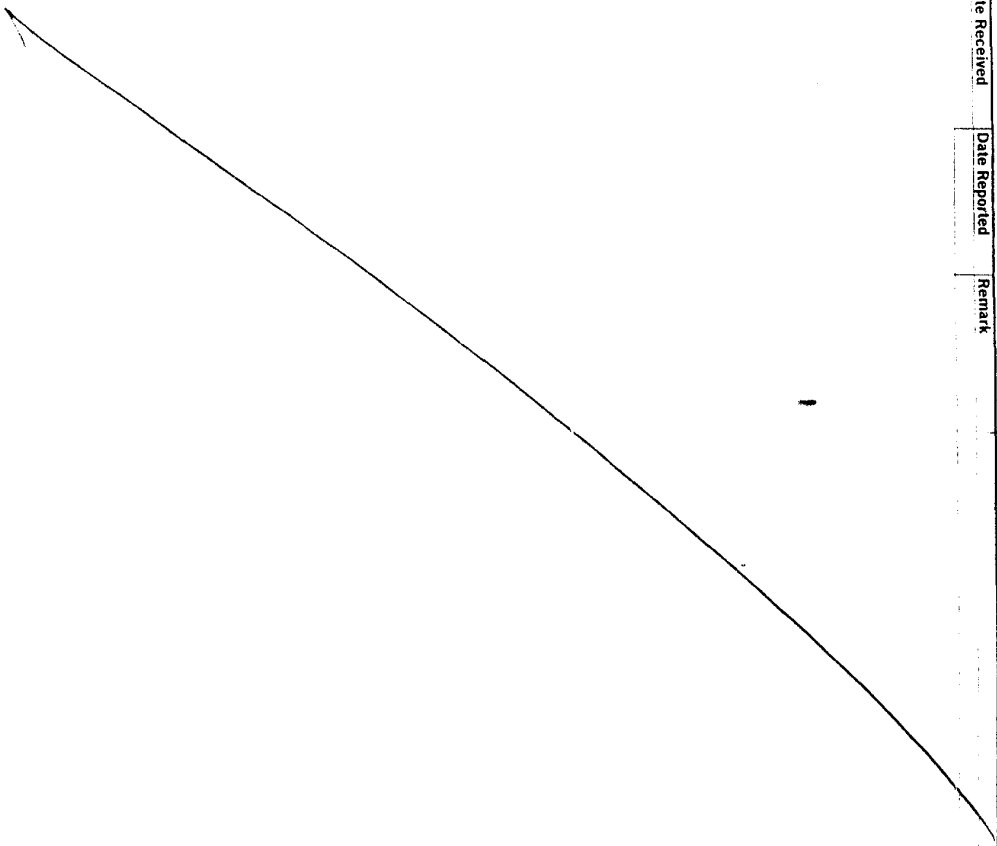
ADULTERATED SPECIMENS

COCH #	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COCA#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC #	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
							

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COCC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COG#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
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ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COA#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

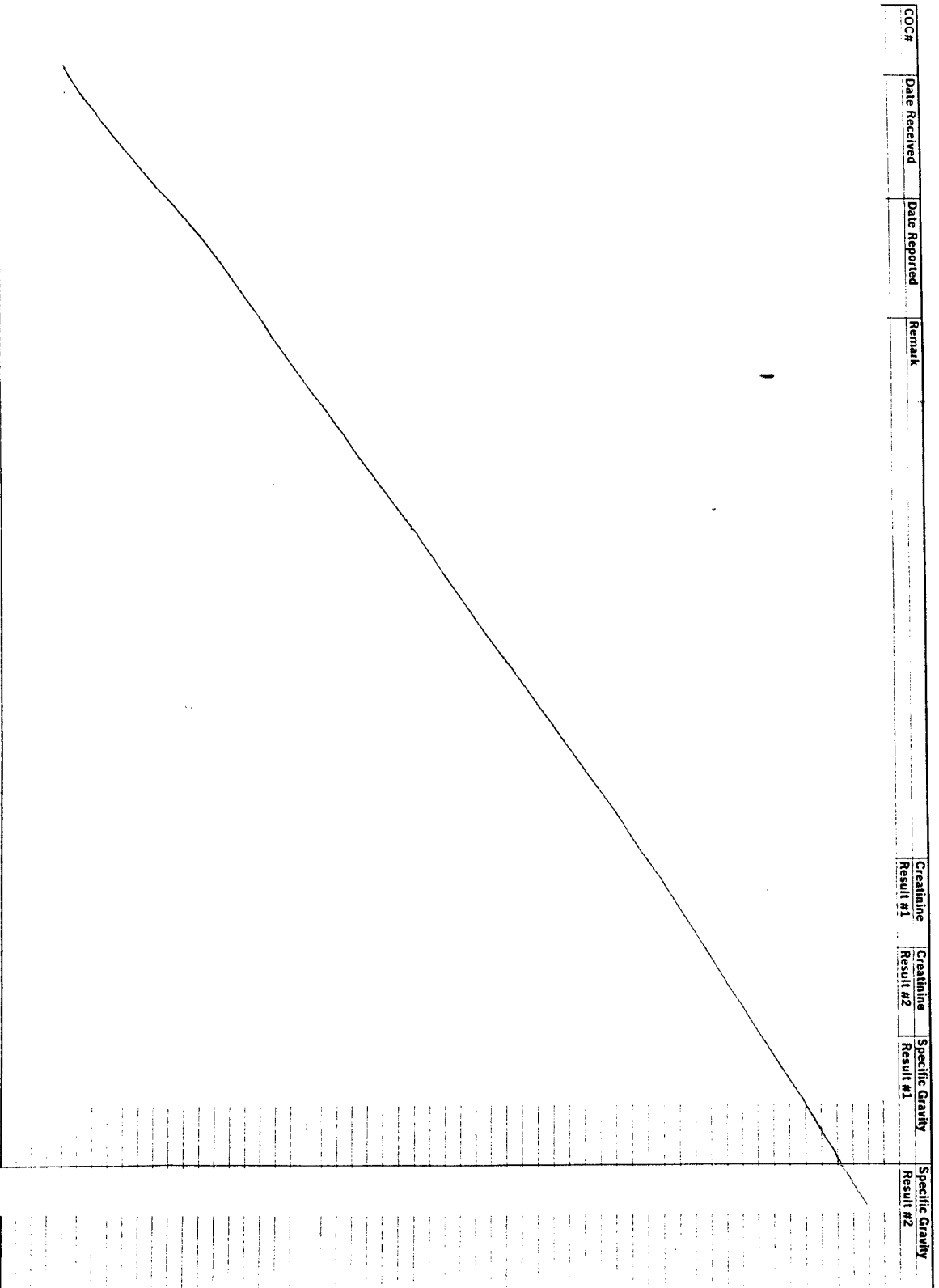
ADULTERATED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
			1				

SUBSTITUTED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

SUBSTITUTED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
							

SUBSTITUTED SPECIMENS

COC#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2
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SUBSTITUTED SPECIMENS

CO#	Date Received	Date Reported	Remark	Creatinine Result #1	Creatinine Result #2	Specific Gravity Result #1	Specific Gravity Result #2

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 13, 2000

0325
Dr. Michael A. Peat
Dr. Lance Presley
LabOne Inc.
10101 Renner Boulevard
Lenexa, KS 66219

Dear Dr. Peat and Dr. Presley:

The enclosed critique was developed from the inspection report associated with the November 13-16, 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:

Drs. Peat and Presley
Page 2 of 4
12/13/00



Drs. Peat and Presley
Page 3 of 4
12/13/00



Drs. Peat and Presley
Page 4 of 4
12/13/00

The laboratory must submit documentation that corrective actions have been implemented to address the other issues raised **within 30 calendar days**. 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. **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 Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt325

INQUIRY TO MRO

Lab Number _____

Name of person contacted at MRO office: _____

Phone Number: () _____

Specimen ID Number: _____

MRO Disposition:

- Substituted, **substitution admitted by donor during interview**
- Substituted, **substitution denied by donor during interview**
- Substituted, **substitution not admitted or denied during interview**
- Substituted, **donor not contacted**
- Substituted, **no comments regarding donor contact**
- Refusal to test**
- Interpreted as negative by MRO**
- Records not available from MRO**
- Cancelled, **medical explanation**
- Cancelled, **other (briefly explain)** _____
- Other (briefly explain)** _____

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0325
Document No: Final

Laboratory: LabOne, Inc.

Location: Lenexa, KS

Document Reviewed: Specimen Validity Testing Inspection Report

Date: 13 November 2000

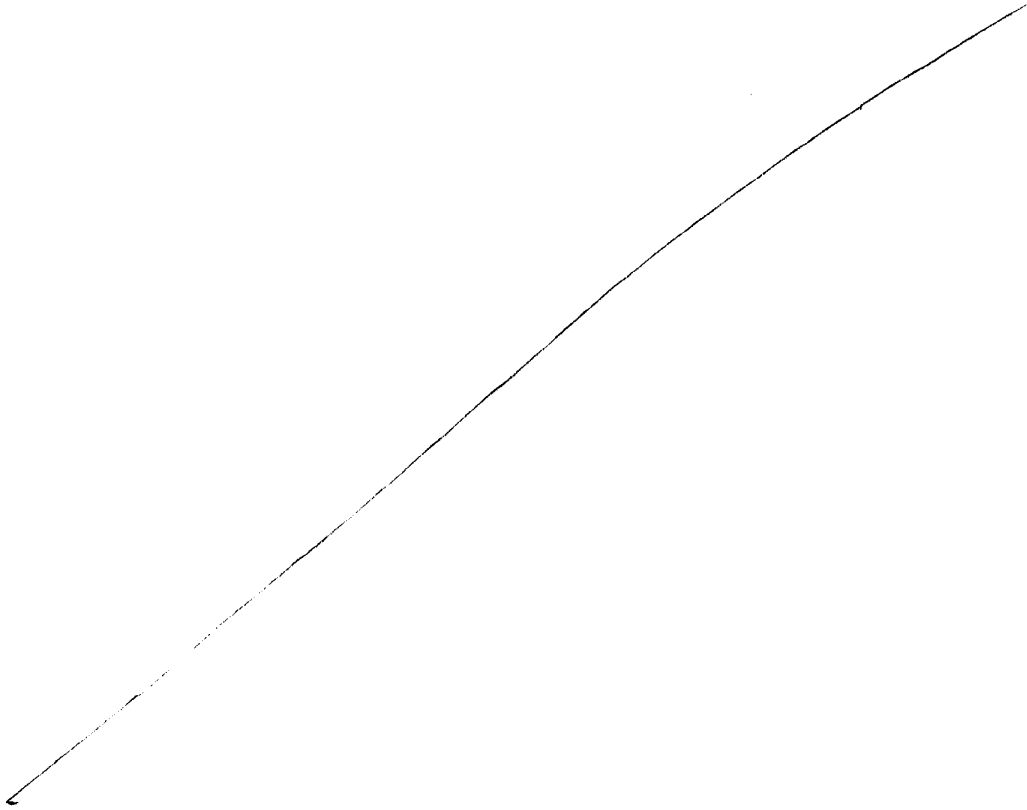
A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

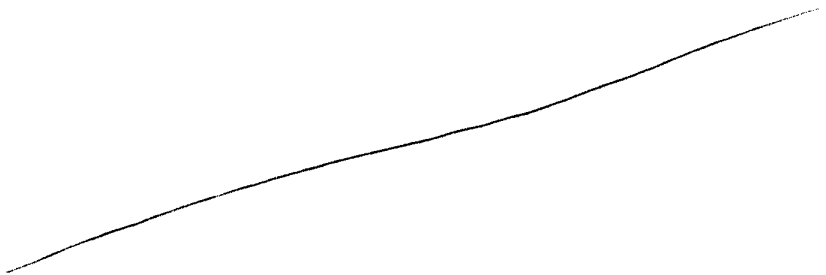
Section E. Standard Operating Procedures - Procedures Manual

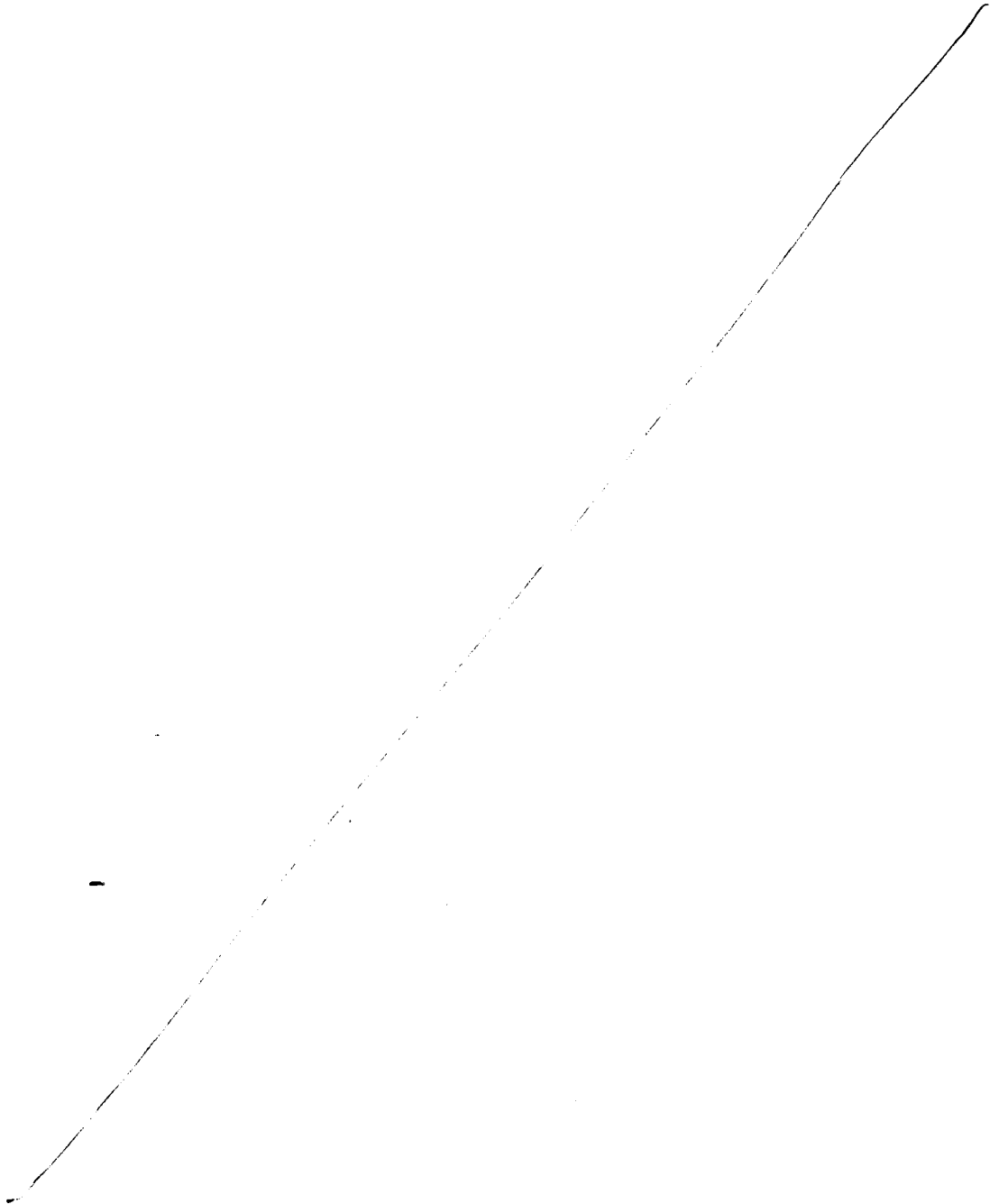
Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance



Section I. Specimen Validity Tests

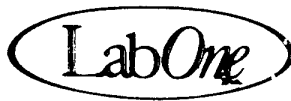




Section K. Records Audit

Section L. Certification and Reporting


Section O. Overall



December 18, 2000

received
SDC 12/19/00

Susan Crumpton
Research Triangle Institute
3040 Cornwallis Road
Research Triangle Park, NC 27709

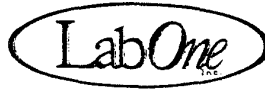
This letter is in reference to your letter dated December 13, 2000, 

Please call me at 1-800-873-8845, ext. 1626 if you have any questions.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lance Presley".

Dr. Lance Presley
Sr. Vice President of Toxicology



received
1/16/01 SDC

LANCE C. PRESLEY, Ph.D., DABFT
Senior Vice President, Toxicology

January 11, 2001

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

Dear Ms Crumpton,

Enclosed you will find the requested documentation in response to your letter of December 13, 2000. Your letter gave the critique of our specimen validity testing inspection of November 13-16, 2000. As you requested, we are responding to the items as they were listed. Attachments are also labeled according to section.



If you need anything else, please let me know.

Sincerely,



Lance Presley, R.P.



LANCE C. PRESLEY, Ph.D., DABFT
Senior Vice President, Toxicology

January 15, 2001

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

Dear Ms Crumpton,

Enclosed you will find additional requested documentation in response to your letter of December 13, 2000. Your letter gave the critique of our specimen validity testing inspection of November 13-16, 2000. As you requested, we are responding to the items as they were listed. Attachments are also labeled according to section.

These were inadvertently left out from the Friday letter. If you need anything else, please let me know.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lance Presley".

Lance Presley, R.P.

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

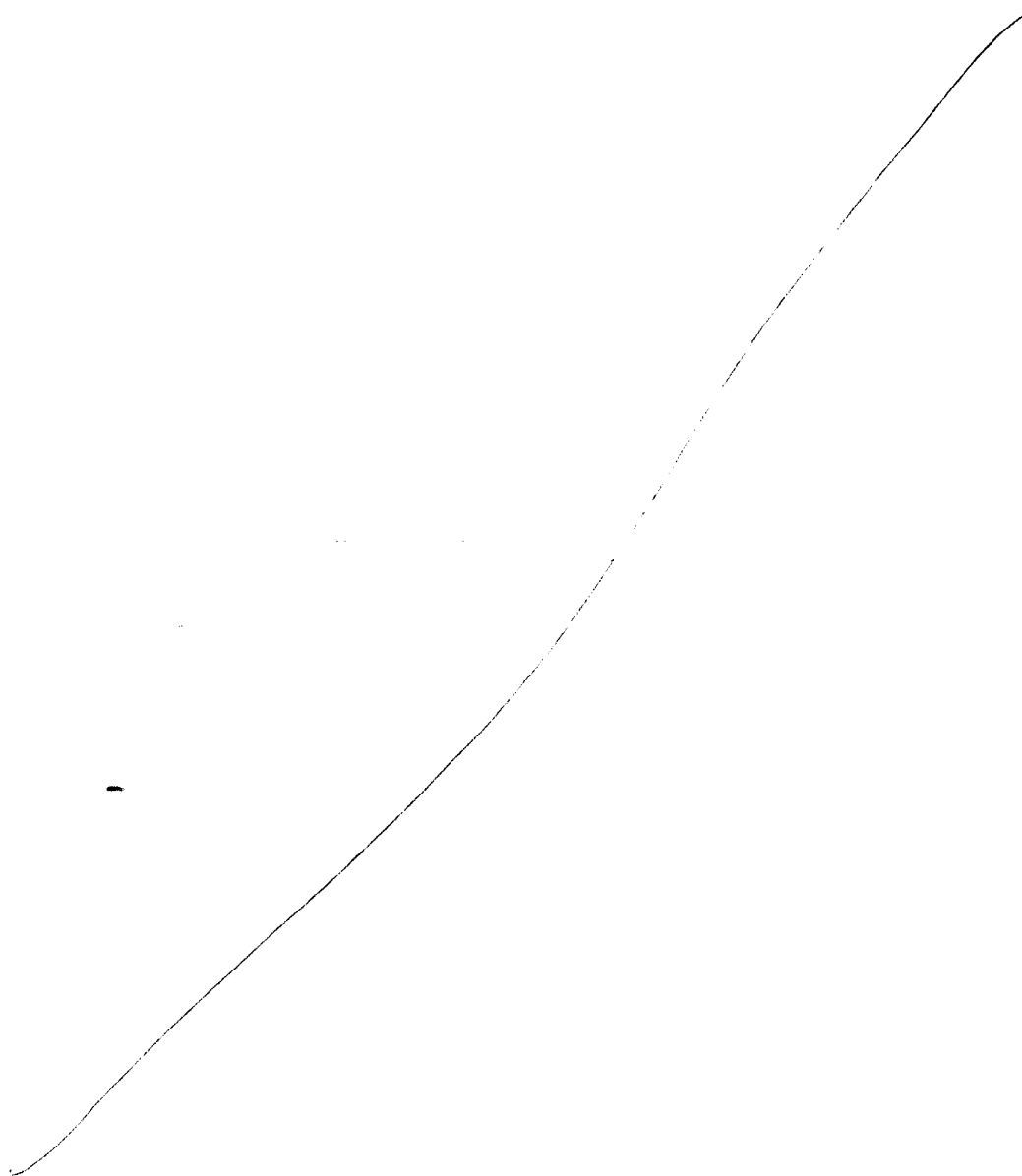
February 14, 2001

0325
Dr. Lance Presley
LabOne Inc.
10101 Renner Boulevard
Lenexa, KS 66219

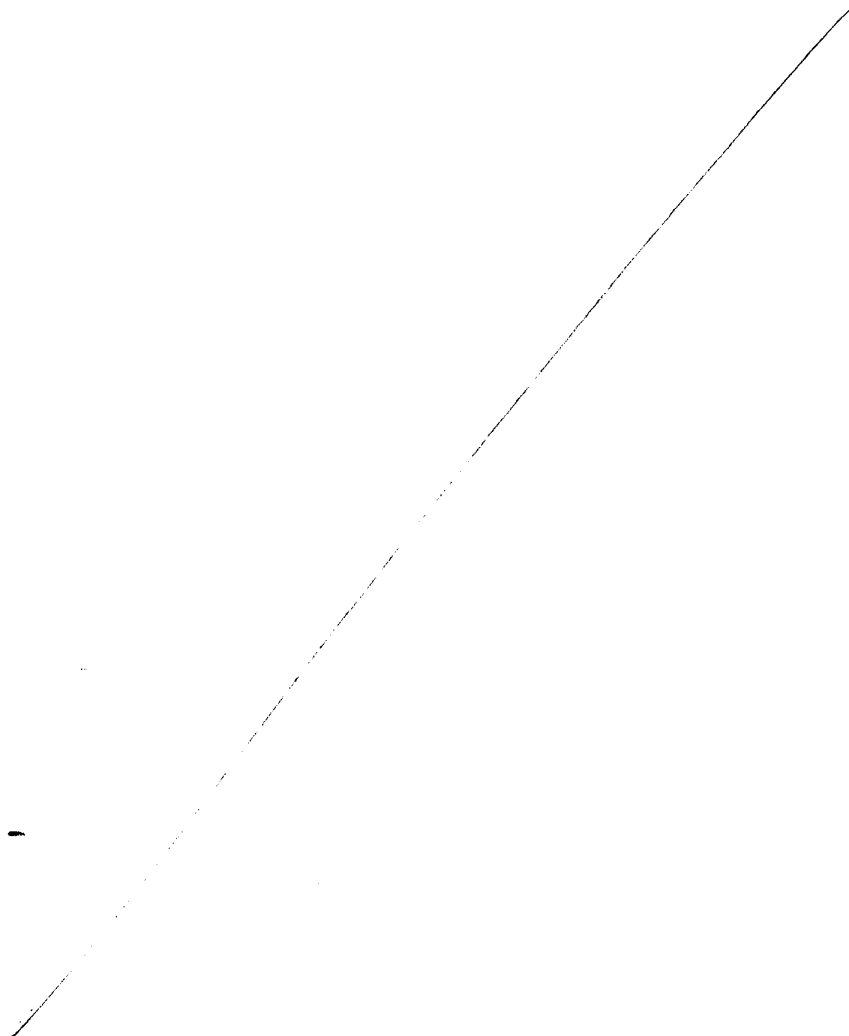
Dear Dr. Presley:

We have reviewed the material provided in your correspondence of December 18, 2000, January 11, 2001, and January 15, 2001, submitted in response to issues raised during the November 13, 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 issues remain or were raised during our review of the laboratory's submissions:

Dr. Presley
Page 2 of 4
02/14/01



Dr. Presley
Page 3 of 4
02/14/01



Based upon our review of the material submitted, it appears that the laboratory has taken steps to ensure that its specimen validity testing procedures are in compliance with program guidance. The laboratory must take corrective actions to address the issues

Dr. Presley
Page 4 of 4
02/14/01

outlined above. 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 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) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/SVT0325