

Validity Testing Information Part I

Laboratory Name: Laboratory Corporation of America Holdings
Address: 1904 Alexander Drive
RTP, NC 27709
Responsible Person: Francis M Esposito (Printed Name)
Steve Van Nus

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).

Francis M Esposito
Signature, Responsible Person

10/5/00
Date

Francis M Esposito
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).

Francis Esposito
Signature, Responsible Person

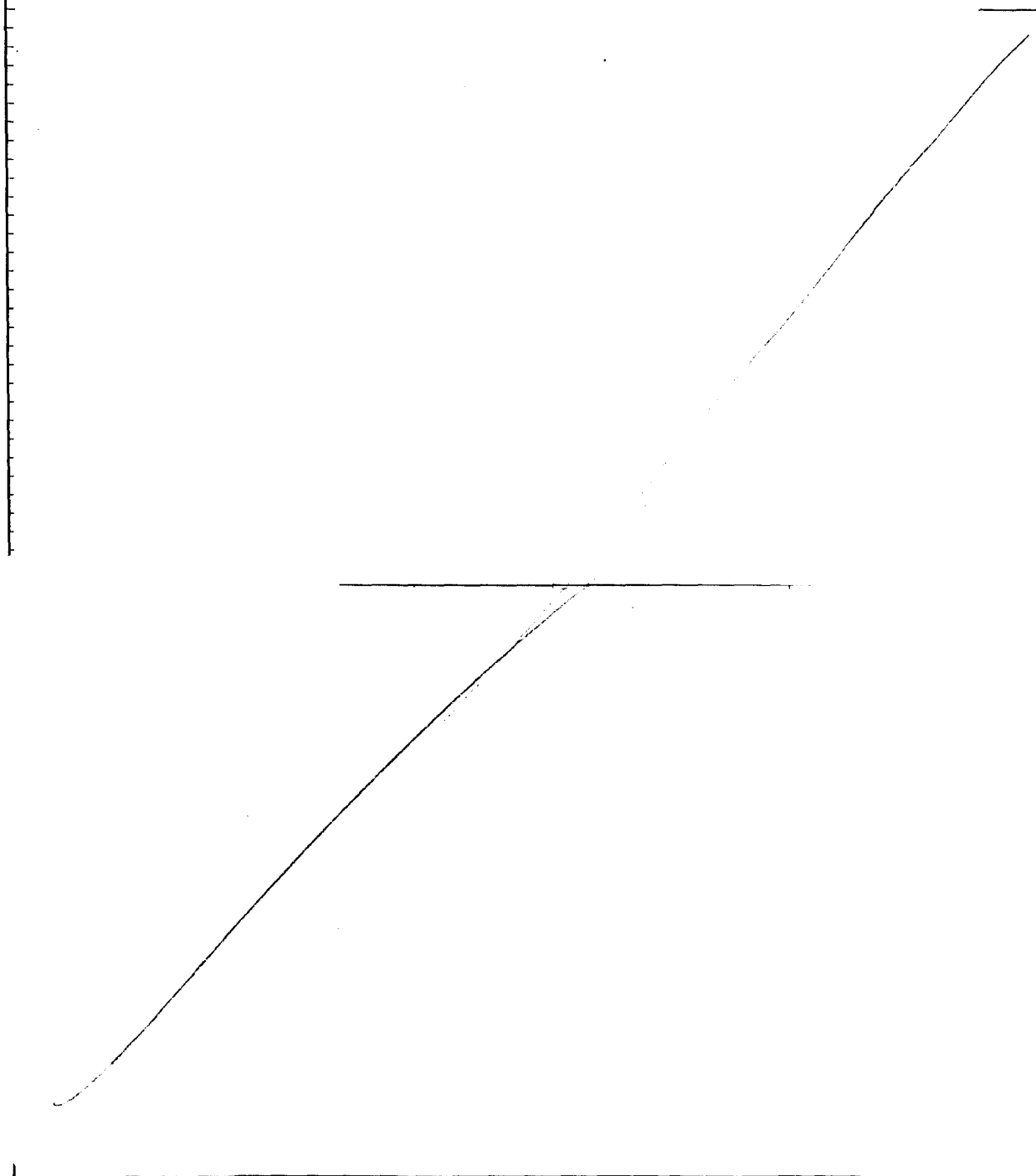
10/16/00
Date

Francis Esposito
Printed Name, Responsible Person

Adulterated or Substituted DOT Samples since 09/28/1998

Company - Laboratory Corporation of America Holdings / Lab - RTP

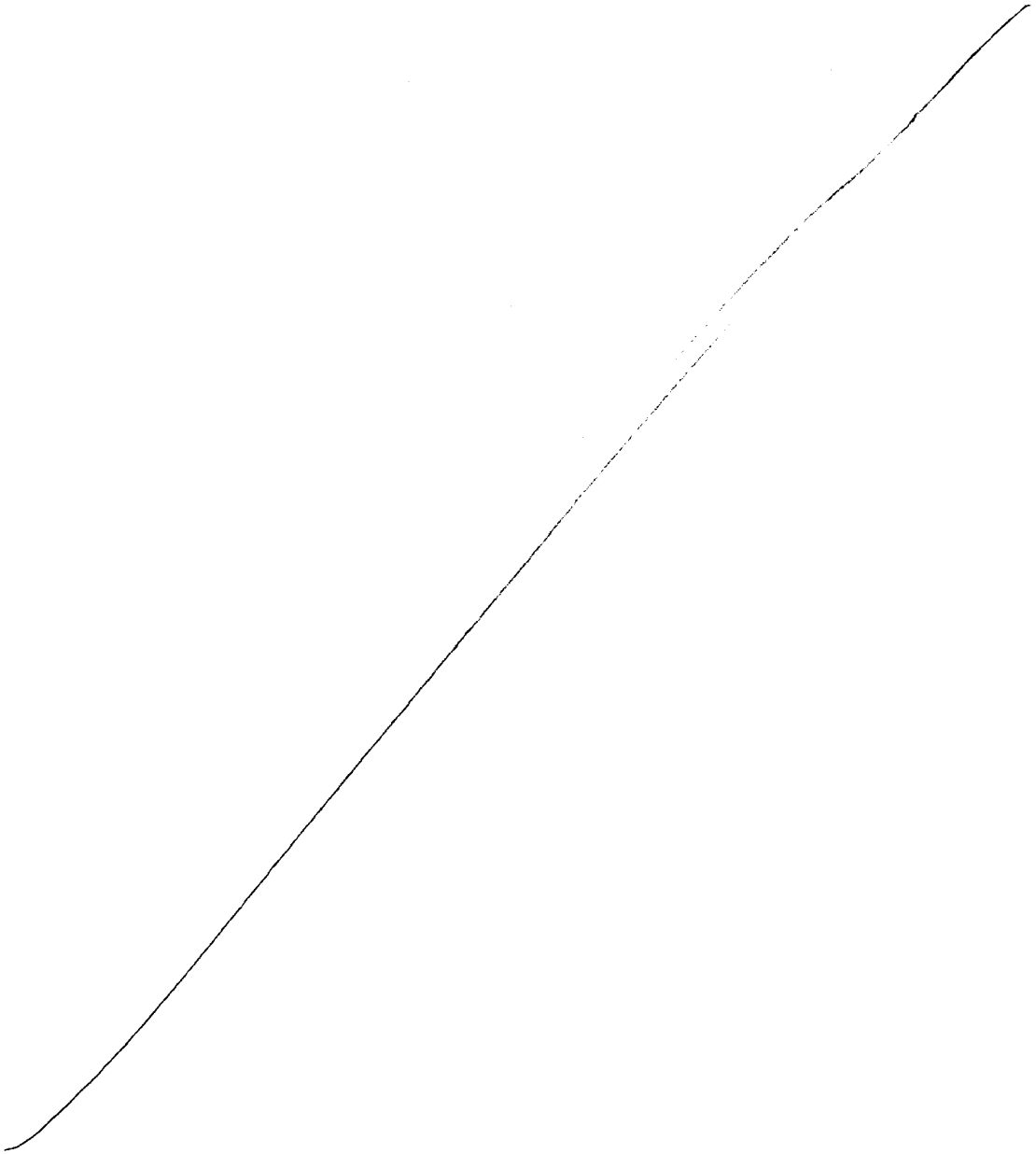
Specimen ID	Accession Nbr	Received Date	Reported Date	Reported Result	Quantitative Results
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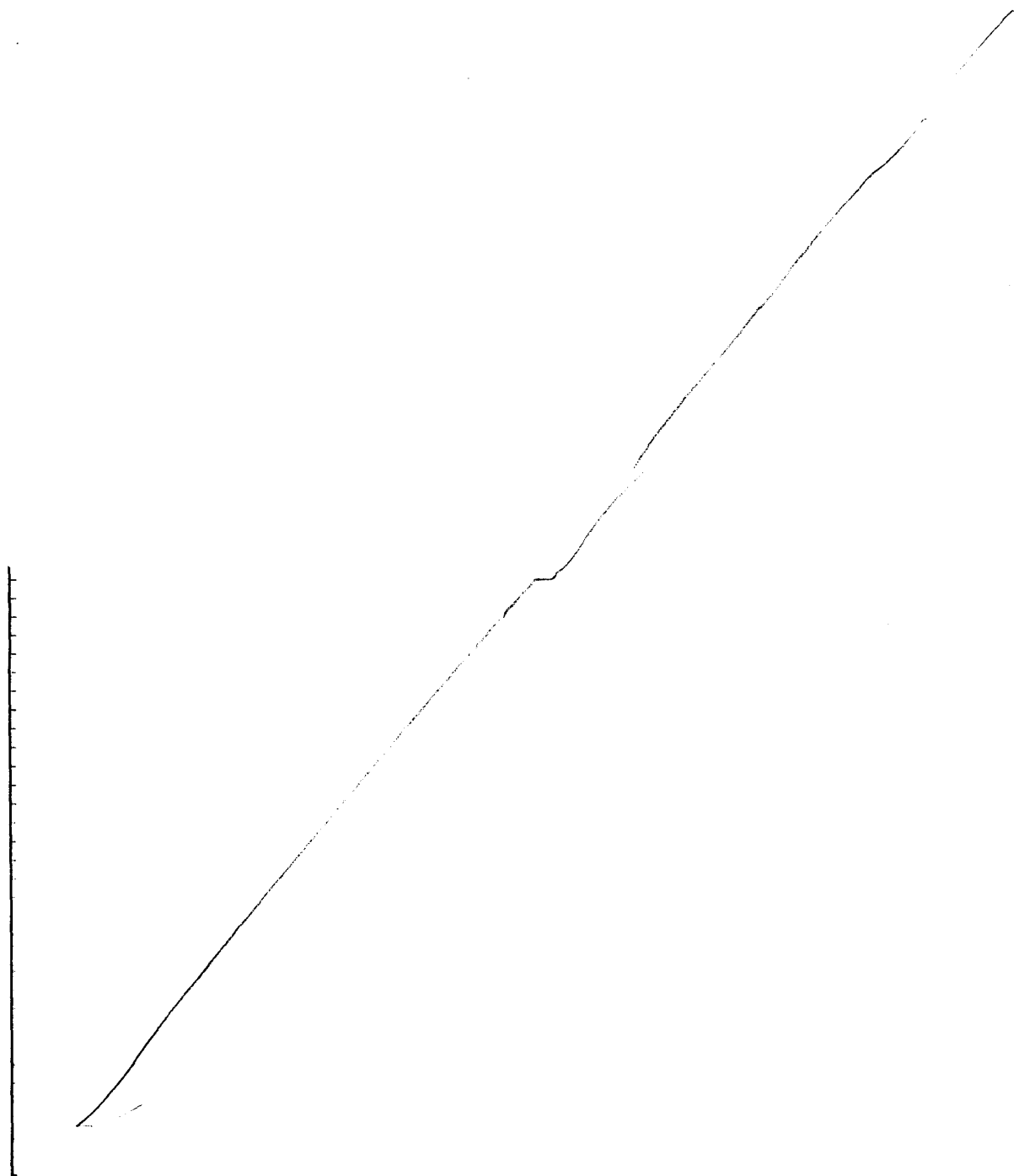
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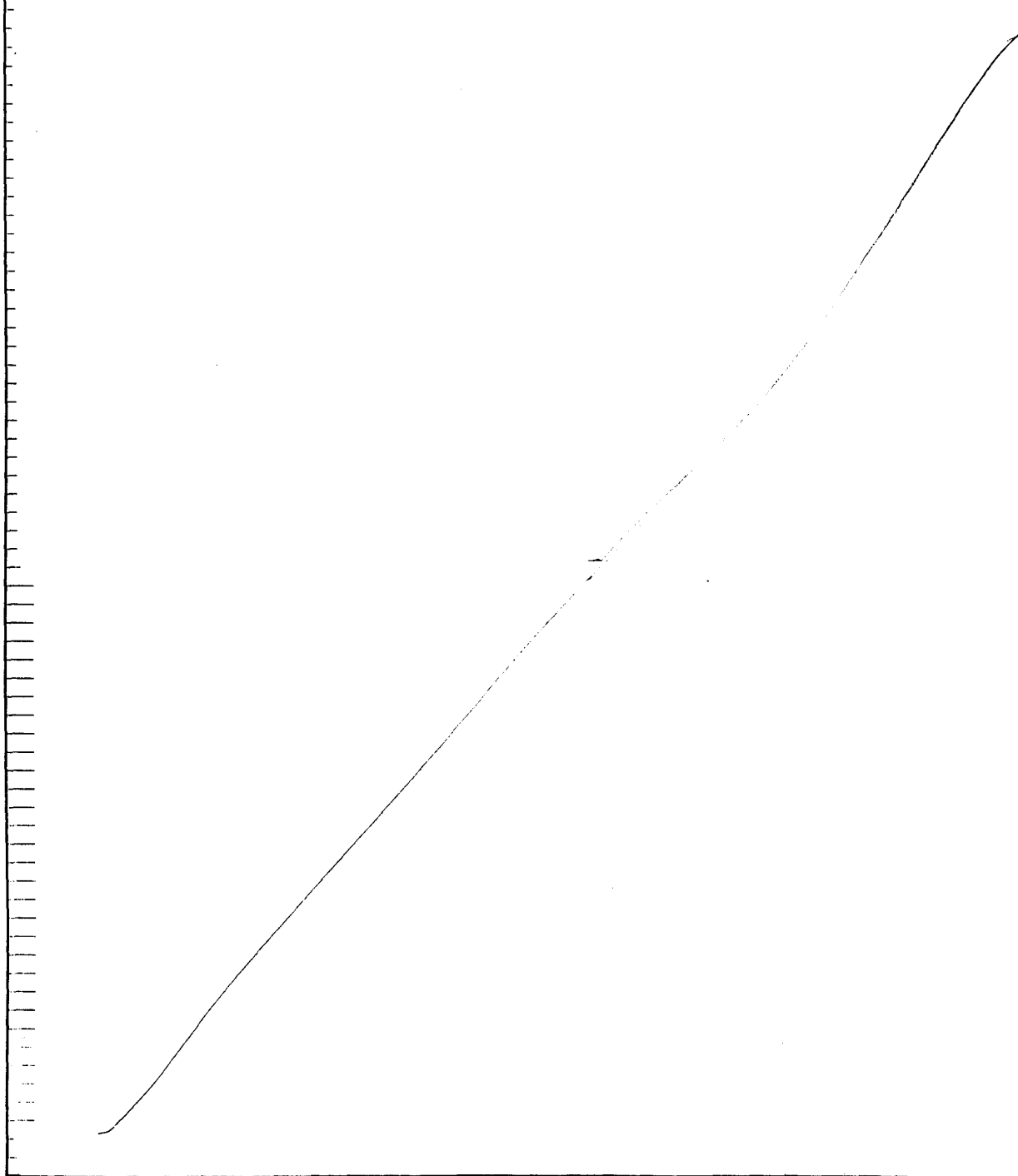
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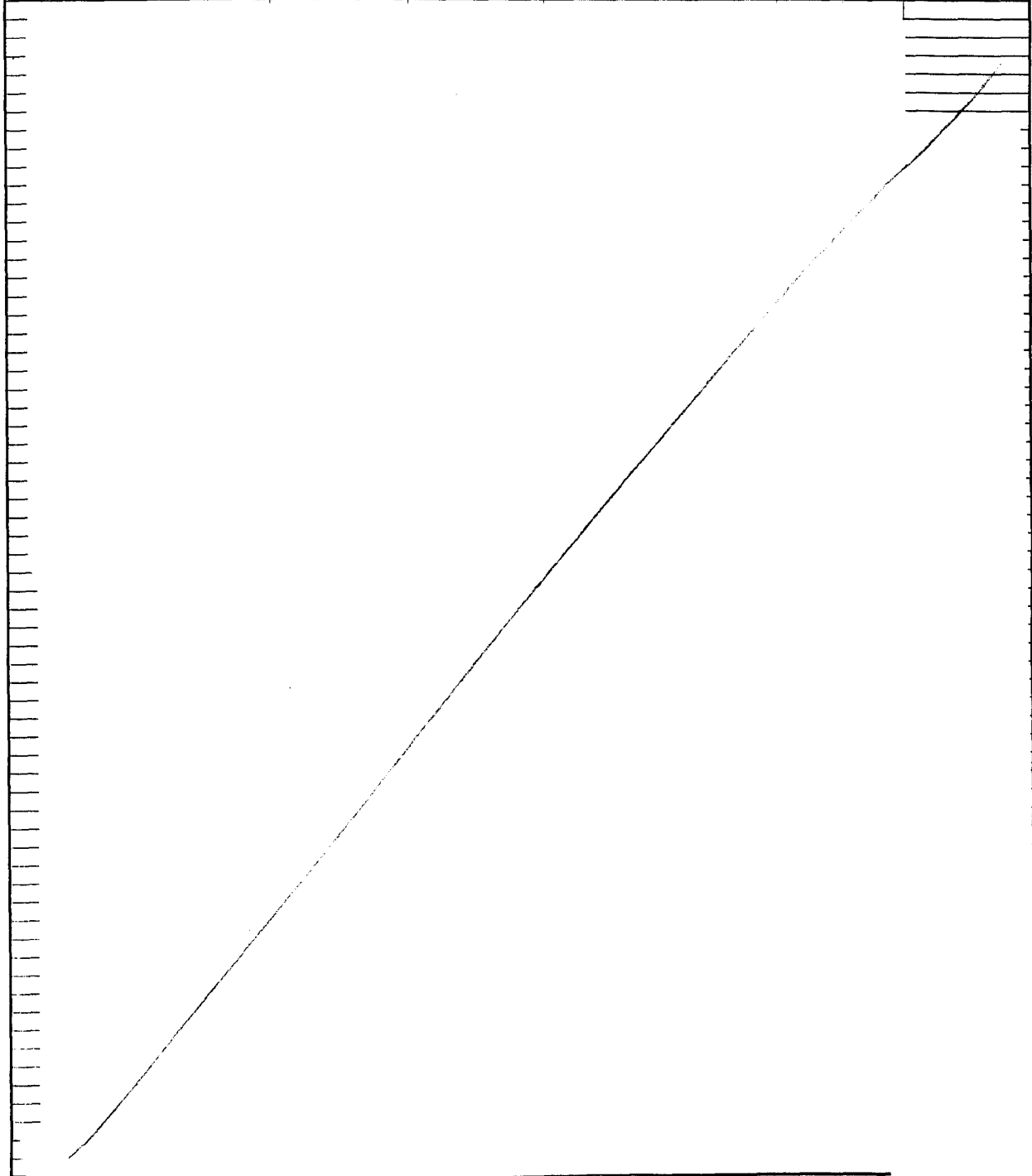
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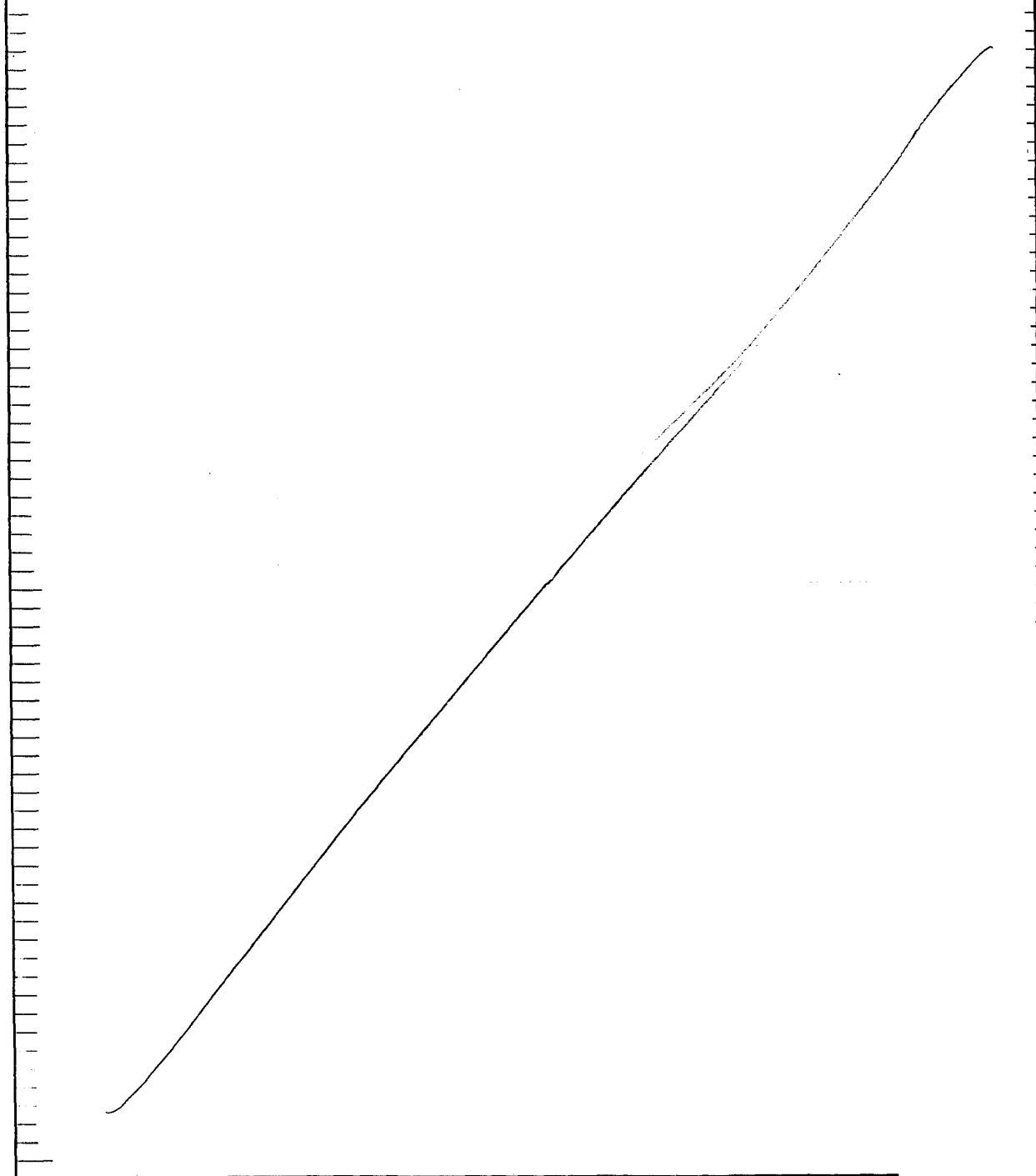
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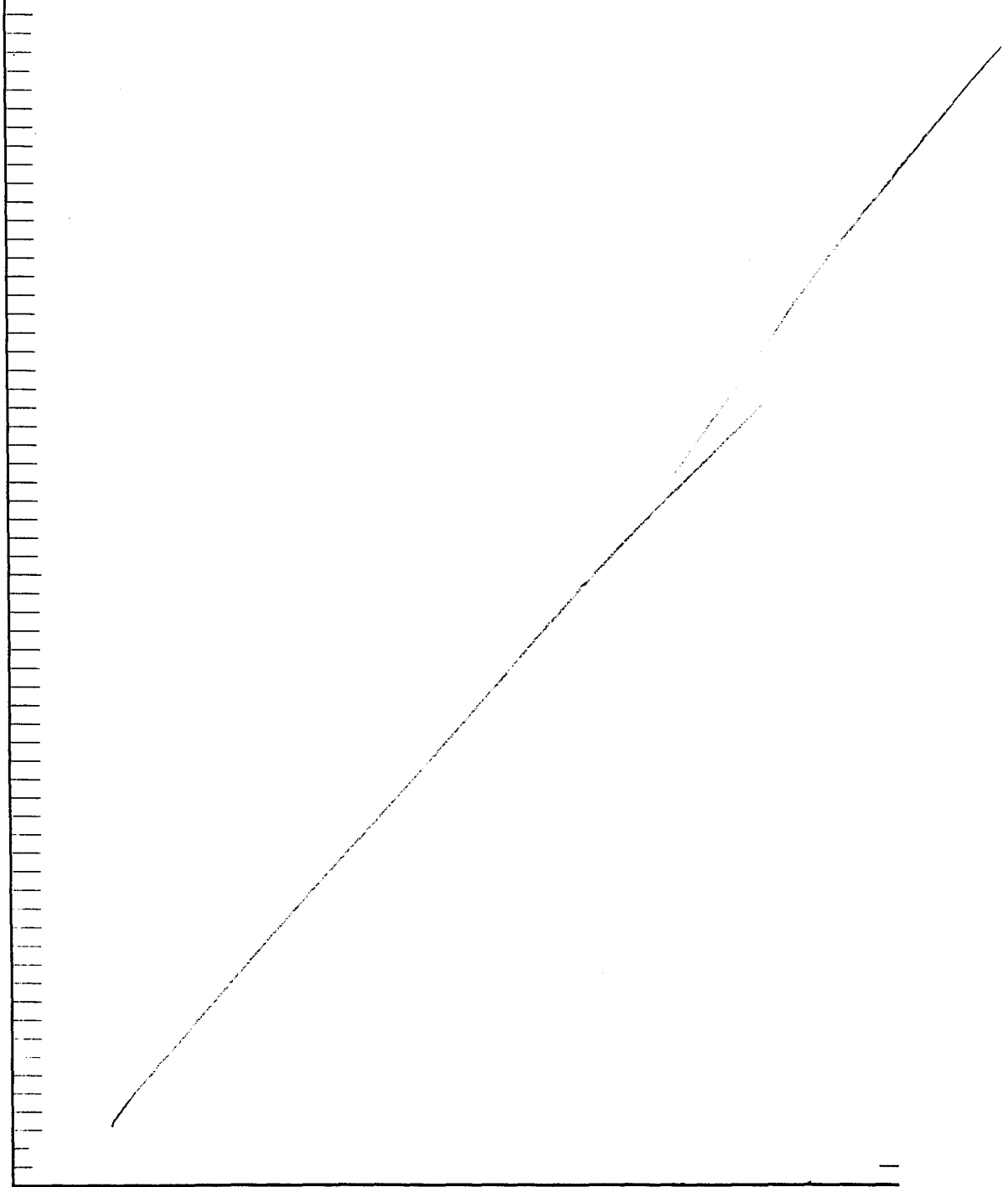
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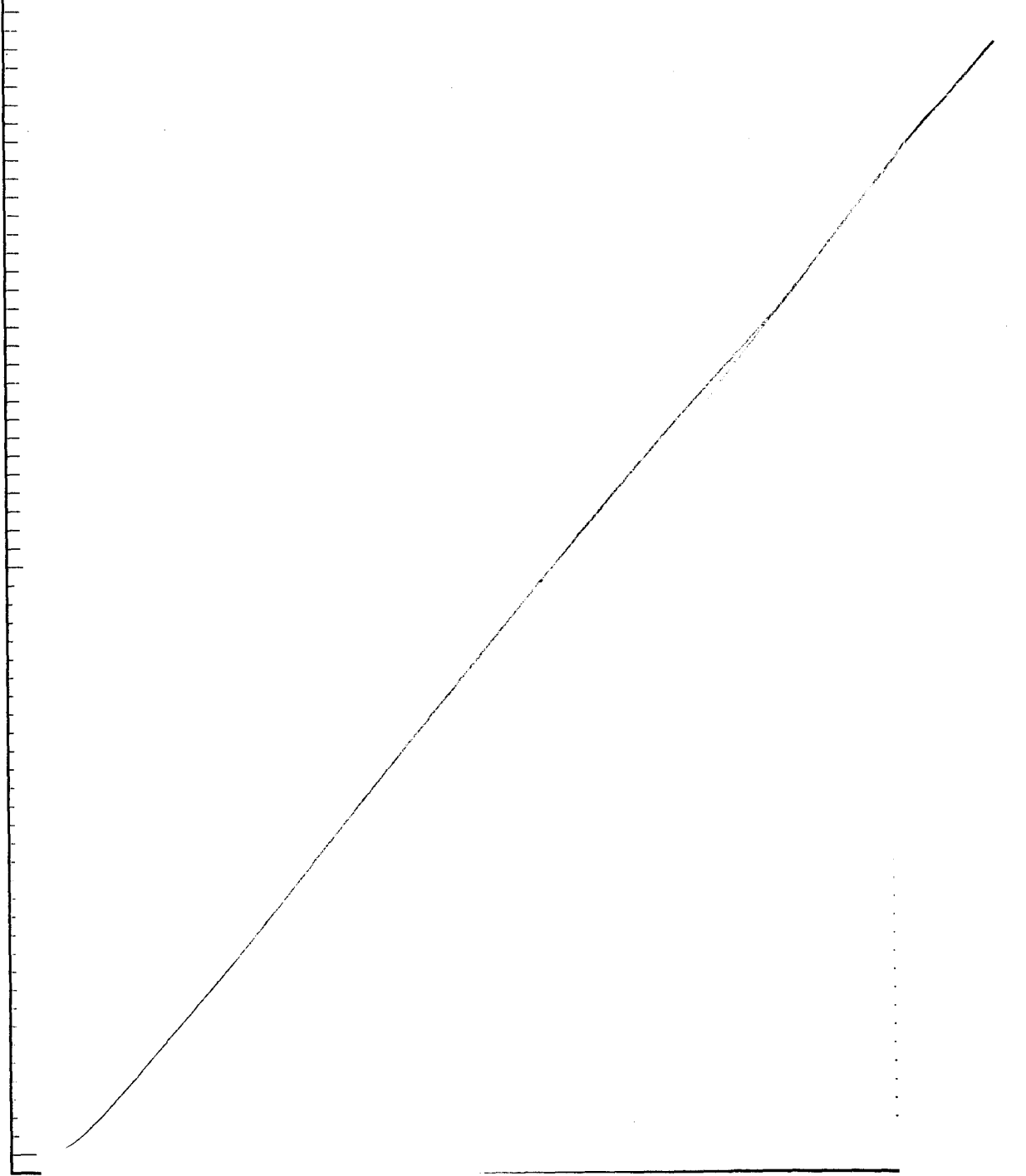
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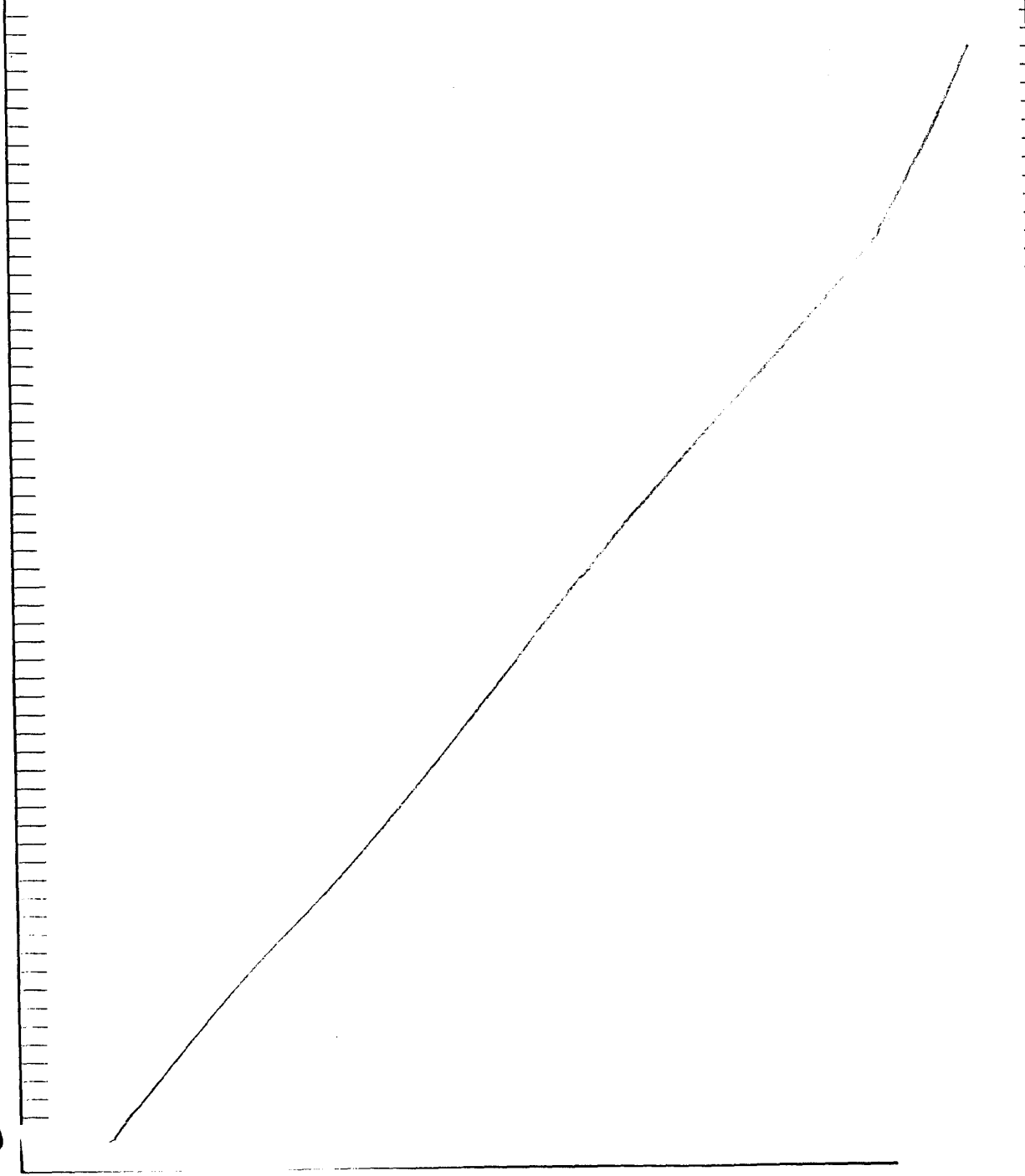
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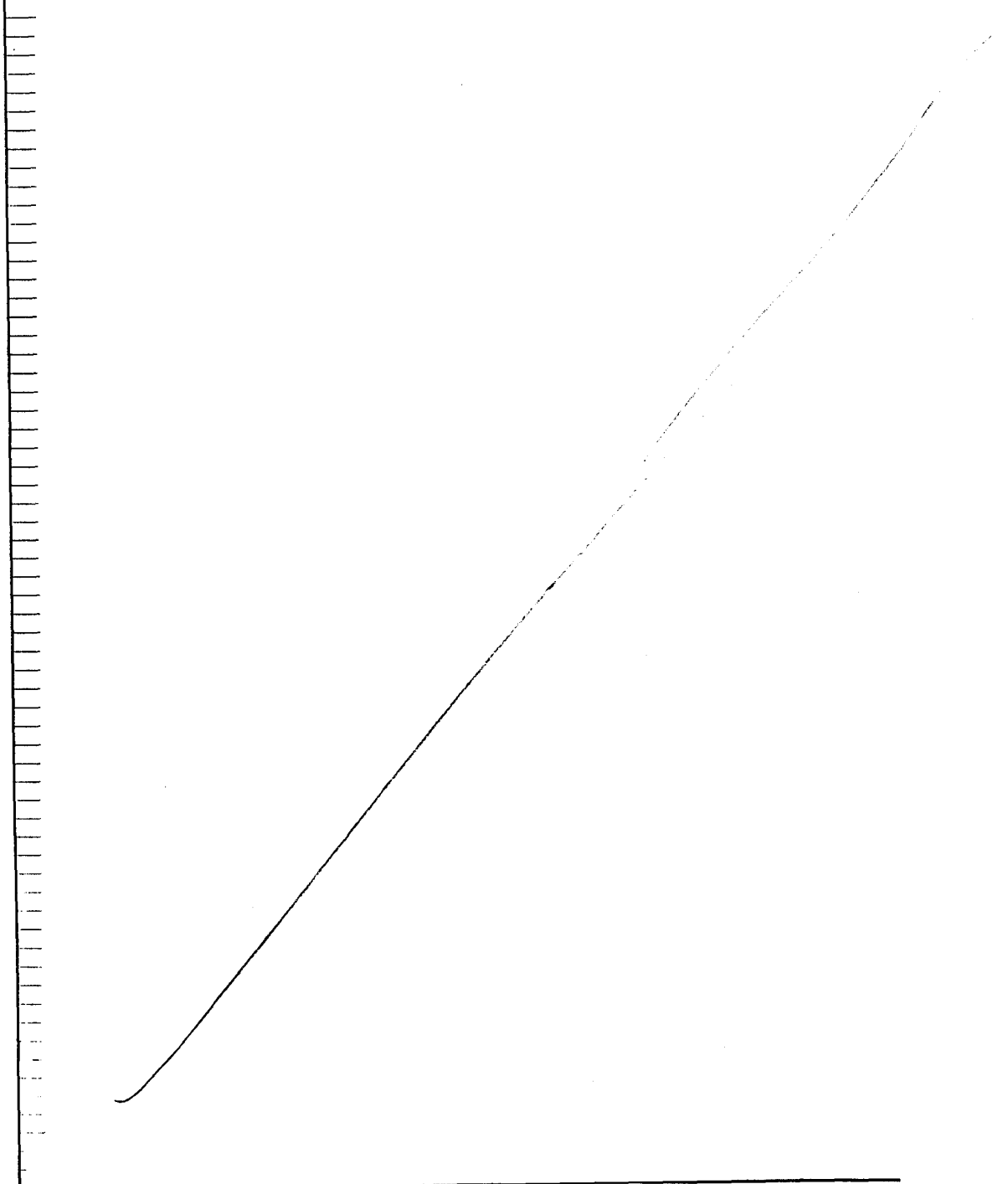
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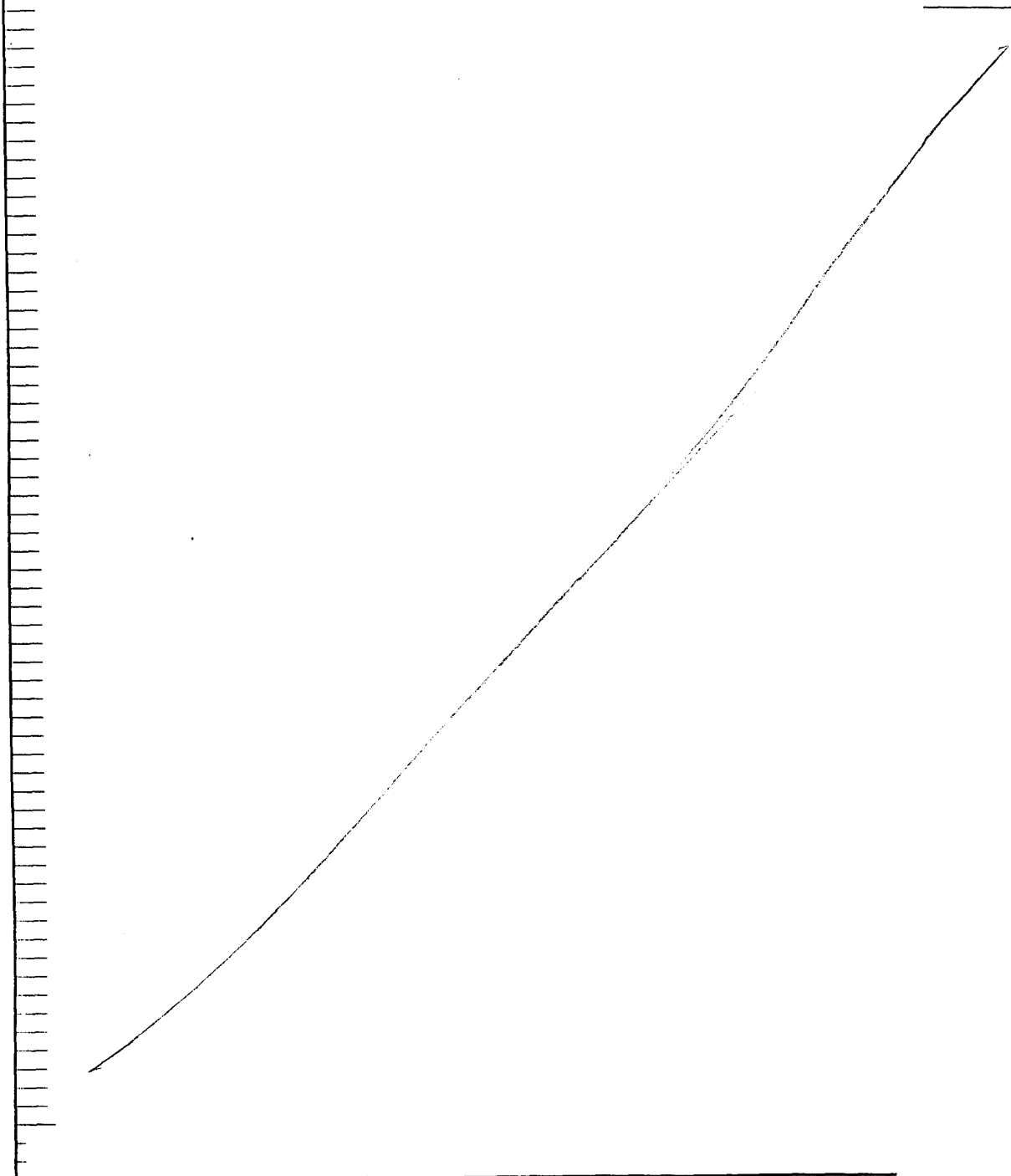
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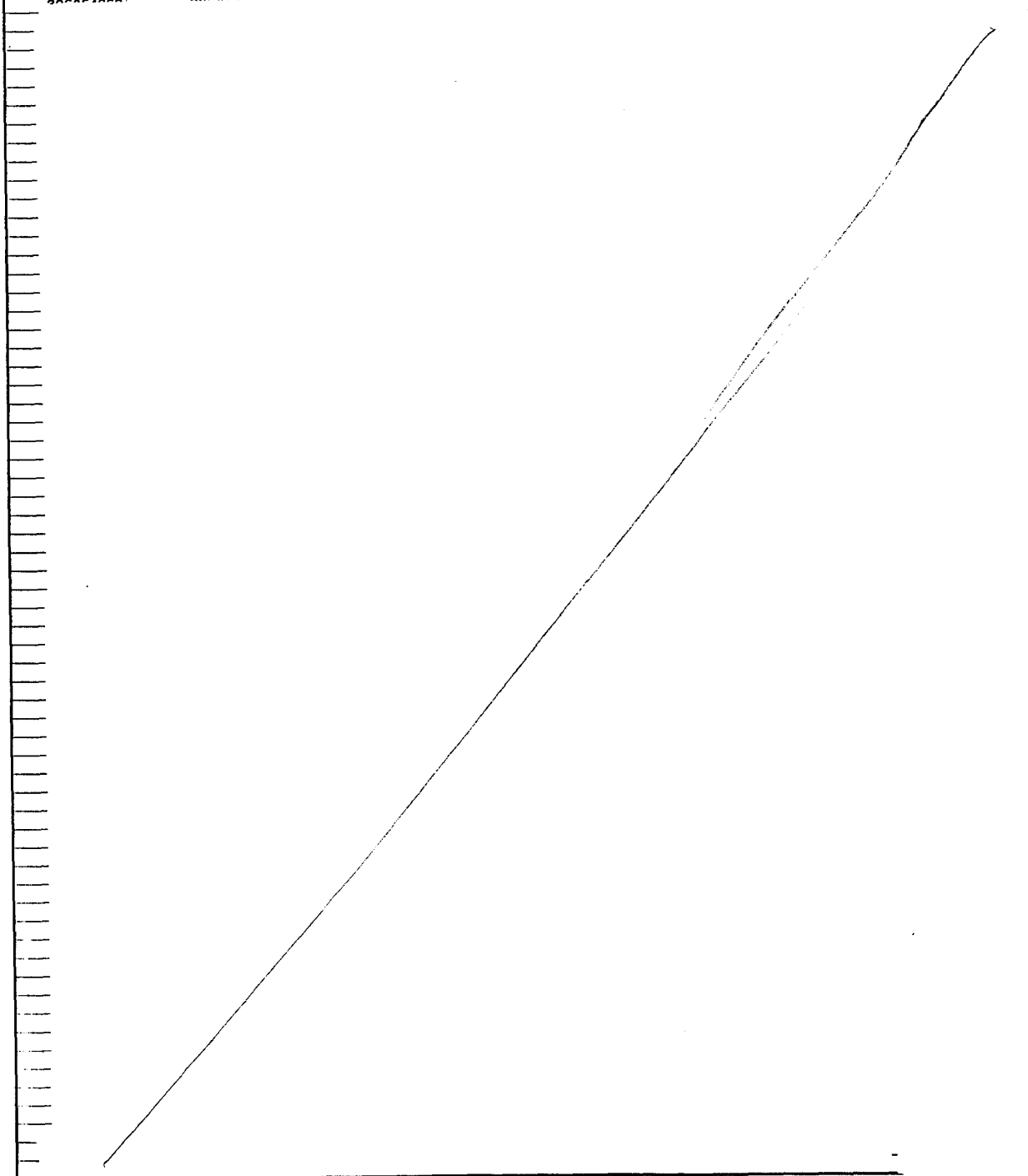
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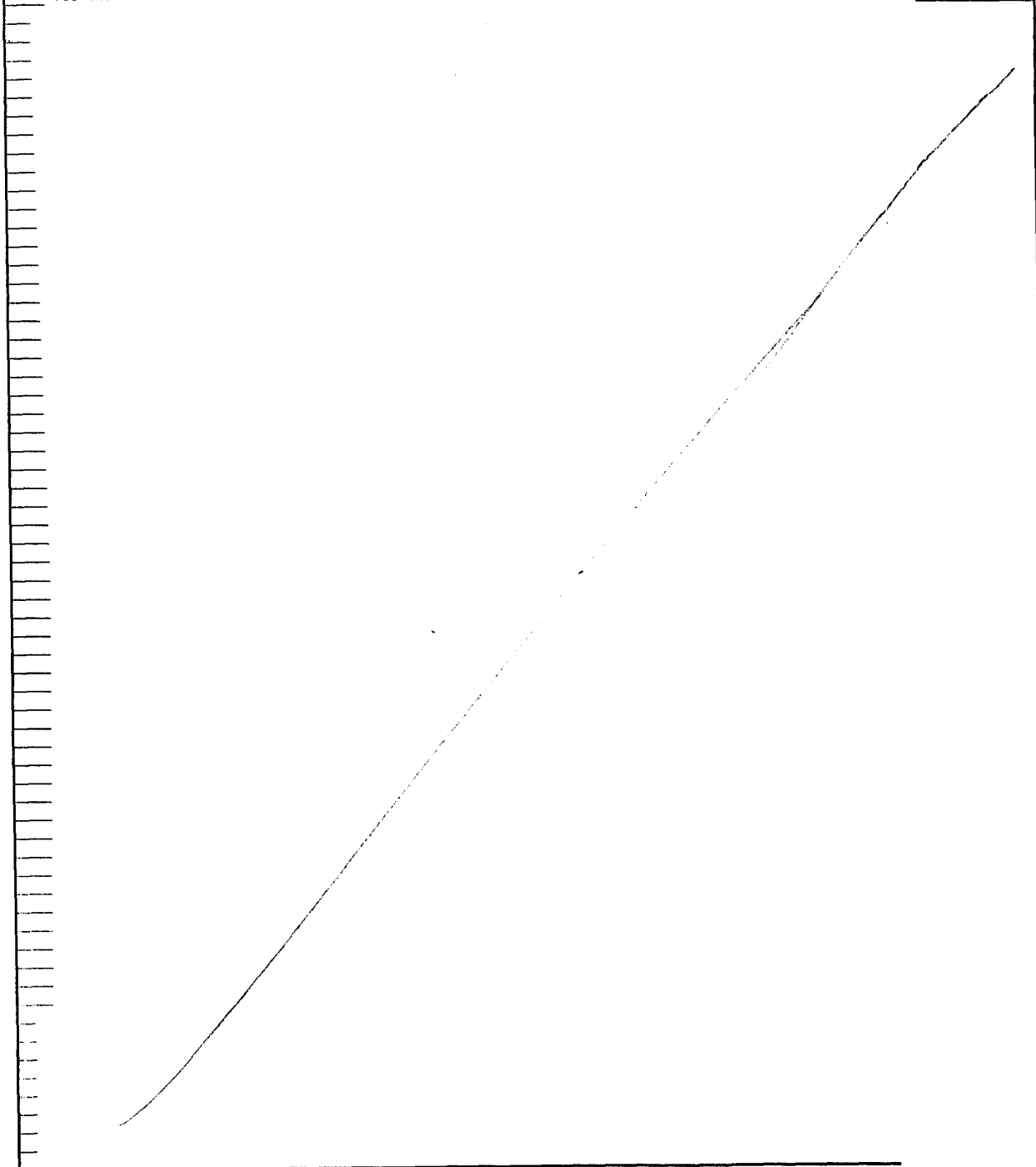


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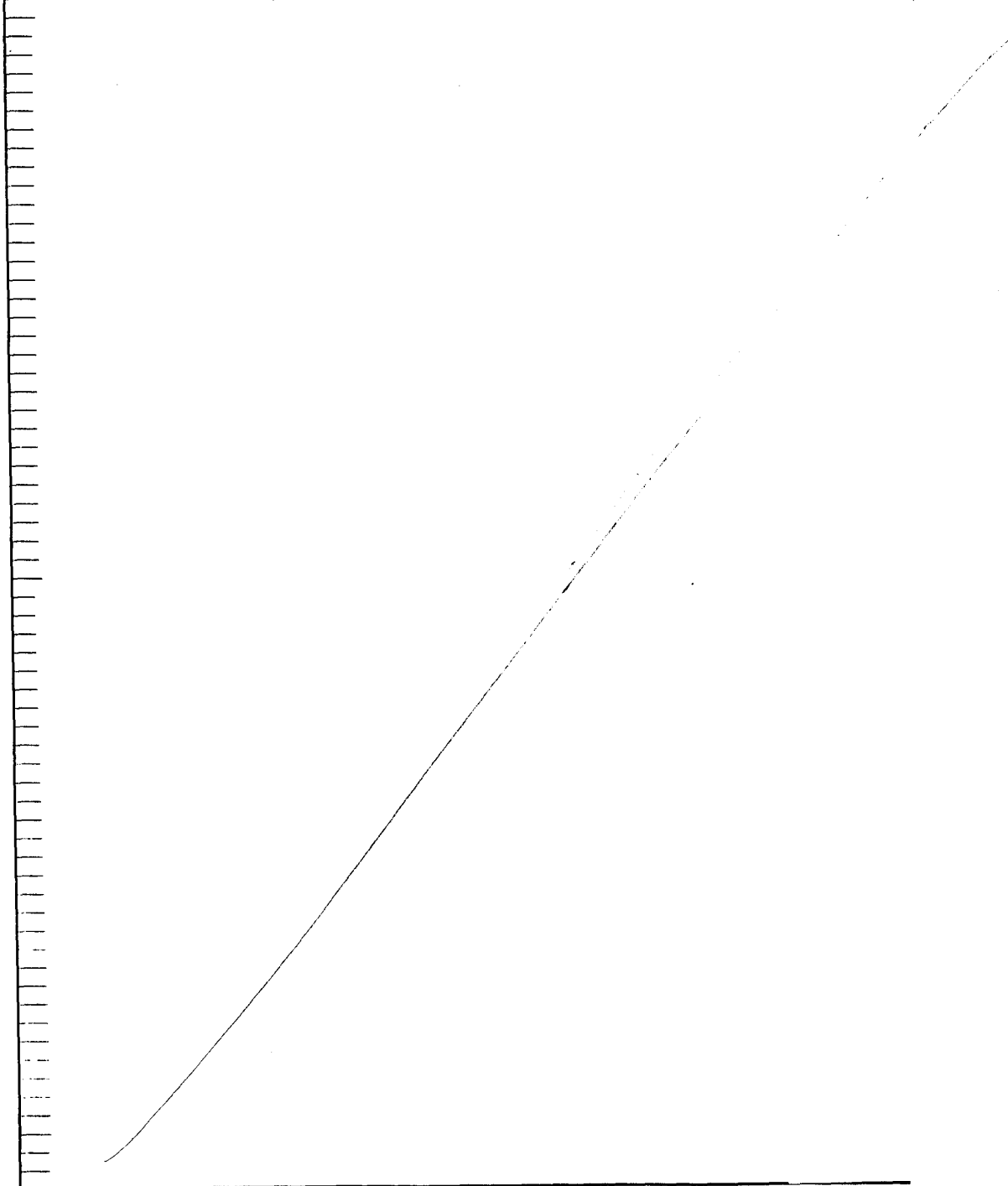
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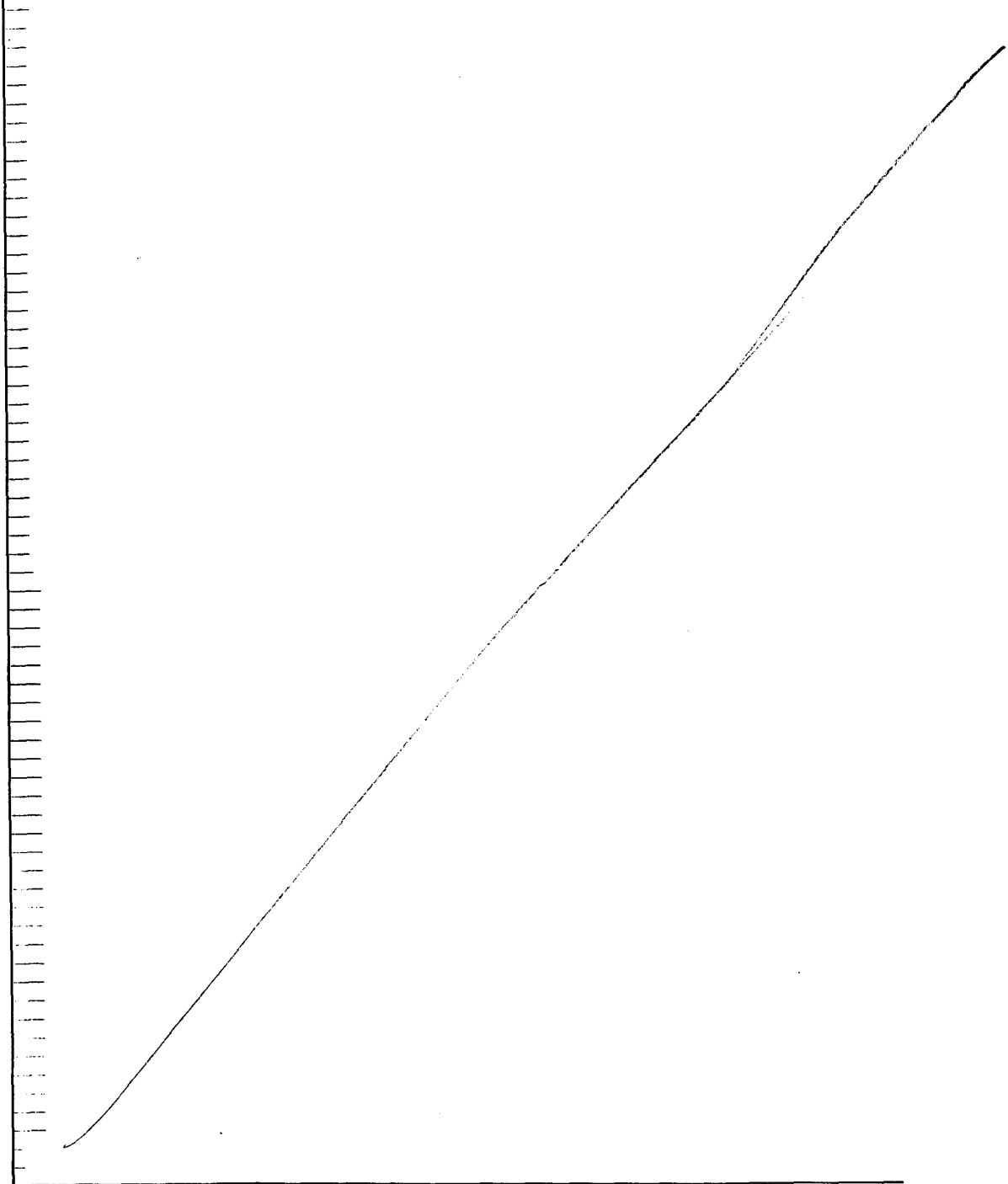
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November 3, 2000

National Laboratory Certification Program

0077
Dr. Francis M. Esposito
Mr. Steve Van Nus
Laboratory Corporation of America Holdings
1904 Alexander Drive
P.O. Box 12652
Research Triangle Park, NC 27709

Dear Dr. Esposito and Mr. Van Nus:

The enclosed critique was developed from the inspection report associated with the October 25-27, 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 issue raised:

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address this issue. 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



Dr. Esposito
Mr. Van Nus
Page 2 of 2
11/03/00

Enclosure

cc: Project Files/svt077

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0077
Document No. Final

Laboratory: Laboratory Corporation of America Holdings

Location: Research Triangle Park, NC

Document Reviewed: Specimen Validity Testing Inspection Report

Date: 25 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



received
12/7/00 SDC

Laboratory Corporation of America® Holdings
PO Box 12652
1904 Alexander Drive
Research Triangle Park, North Carolina 27709

December 6, 2000

Telephone: 800-833-3984
919-572-6900

Research Triangle Institute
National Laboratory Certification Program
Attn: Susan Crumpton
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Crumpton:

Our laboratory has received your letter dated November 3, 2000. Results of this study are enclosed.

If there are any questions, please contact me at 572-7511.

Sincerely,

Francis M. Esposito, Ph.D., DABFT
Laboratory Director

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

December 11, 2000

0077
Dr. Francis M. Esposito
Mr. Steve Van Nus
Laboratory Corporation of America Holdings
1904 Alexander Drive
P.O. Box 12652
Research Triangle Park, NC 27709

Dear Dr. Esposito and Mr. Van Nus:

We have reviewed the material provided in your correspondence of December 6, 2000, submitted in response to issues raised during the October 25-27, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 3, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been completed to address the issues raised. However, the following was noted during our review of the laboratory's submission:



Dr. Esposito
Mr. Van Nus
Page 2 of 2
12/11/00

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

Sincerely,


Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT077