

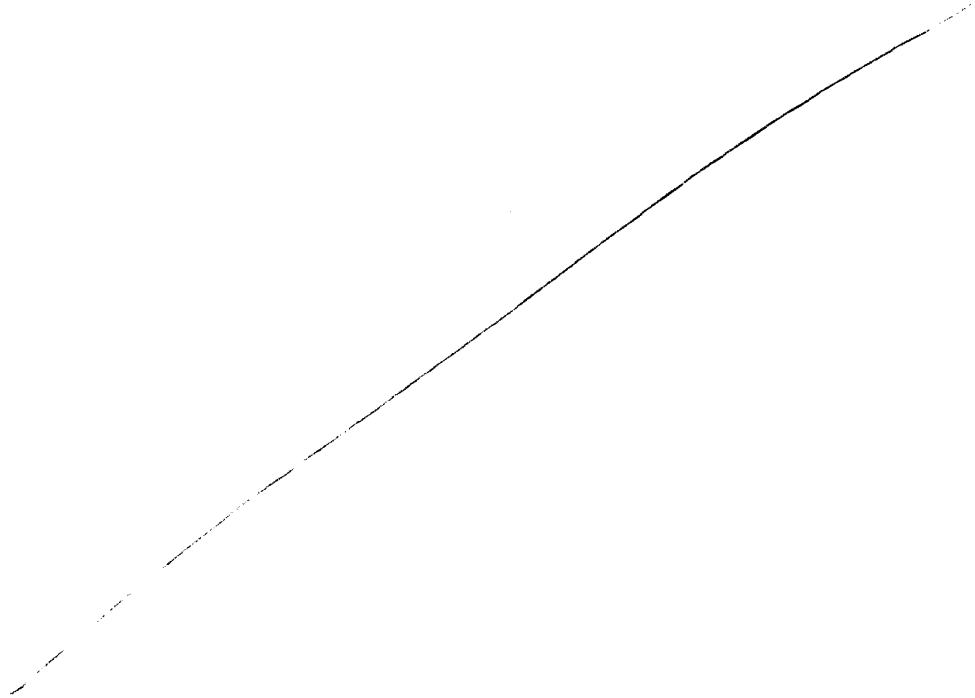


February 4, 1999

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

Dear Dr. Peat:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the eighth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The laboratory must correct/clarify the following issues raised:



20



RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. 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 Baylor at (919) 541-7043.

Sincerely,


Susan D. Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M8



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: LabOne, Inc.

Location: Lenexa, KS

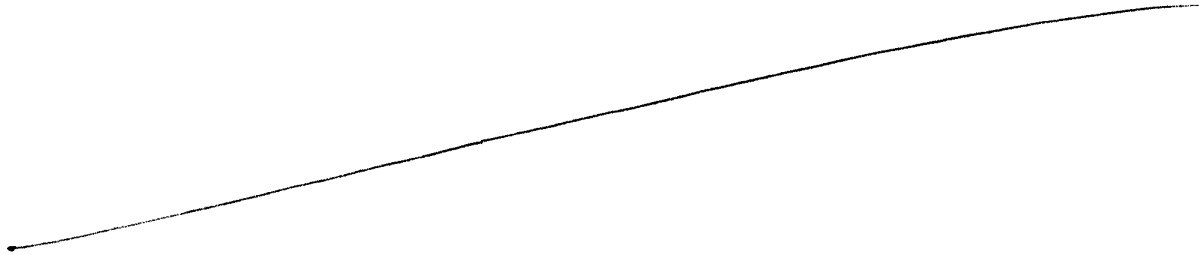
Document Reviewed: Application Form
 Inspection Report #M8
 Other _____

Date: 10 December 1998

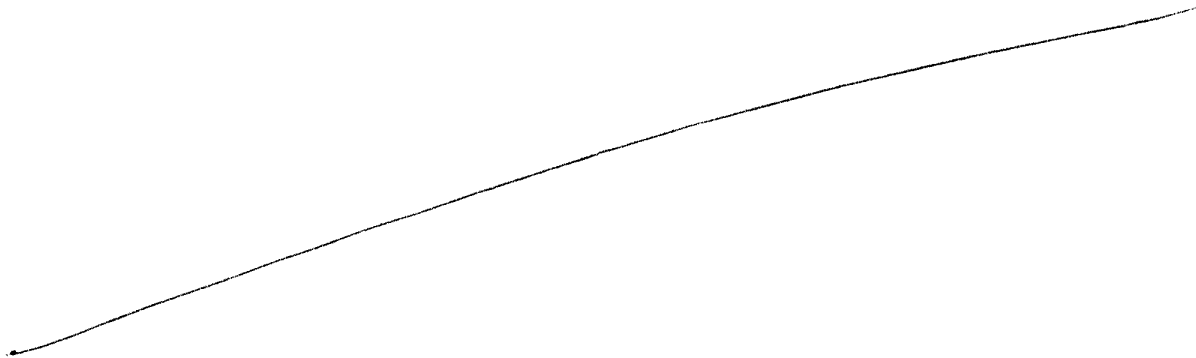
Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.



Section G. Quality Control



Section H. Initial Tests

Section I. Confirmatory Tests



Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel

RESEARCH TRIANGLE INSTITUTE



National Laboratory Certification Program

August 30, 1999

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

Dear Dr. Peat:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the ninth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. However, the laboratory must correct the following issues raised:



RTI is recommending to the Department of Health and Human Services (HHS) that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. 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 Baylor at (919) 541-7043.


Sincerely,


Susan Crumpton
NLCP Inspection Analyst

Dr. Peat
Page 3 of 3
08/30/99

Enclosure

cc: Project Files/M9



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: LabOne, Inc.

Location: Lenexa, KS

Document Reviewed: [] Application Form
 [XX] Inspection Report #M9 Date: 8 July 1999
 [] Other _____

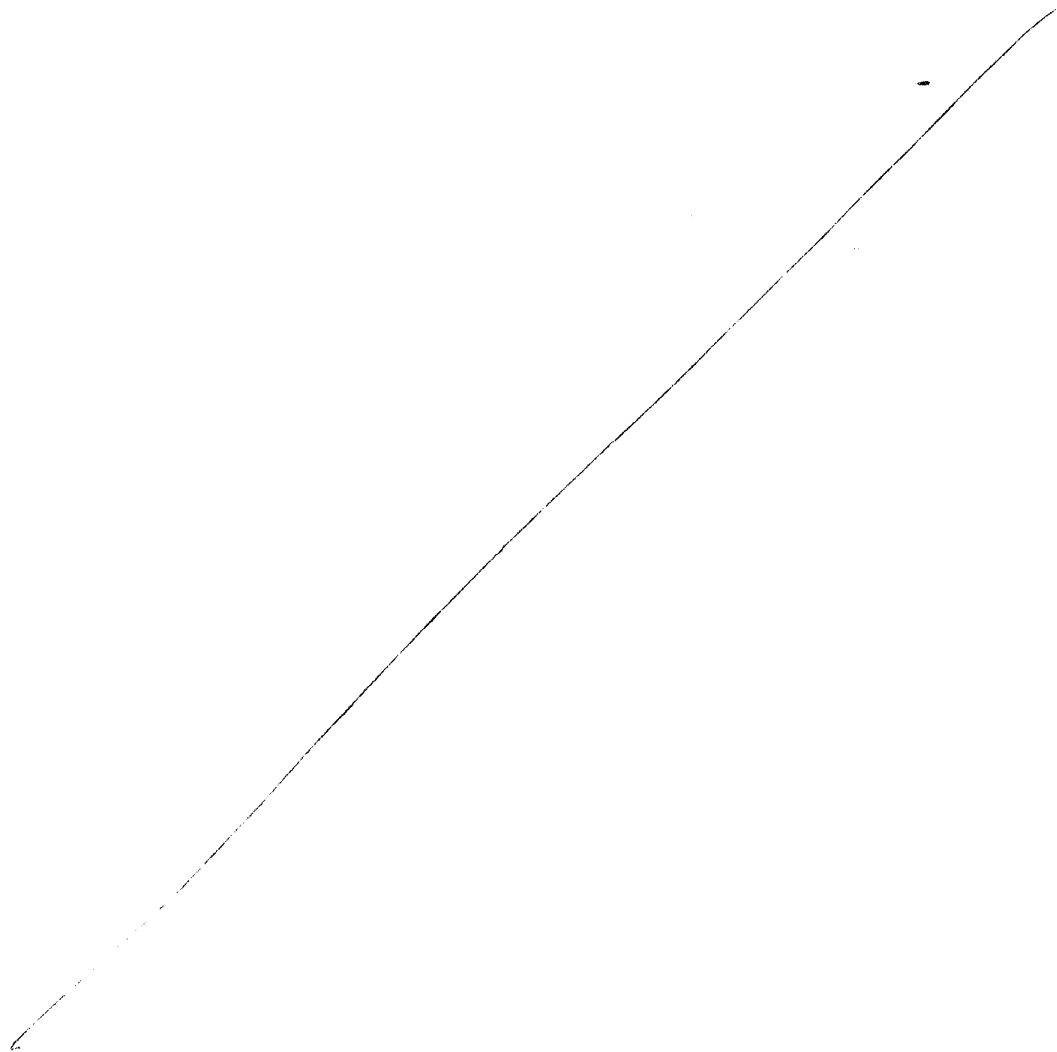
Status: [XX] Highly Acceptable [] Acceptable
 [] Unacceptable [] Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

February 9, 2000

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

Dear Dr. Peat:

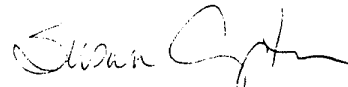
The enclosed critique was developed from the inspection reports of the inspectors who conducted the tenth maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



RTI is recommending to HHS that the laboratory's certification be continued based upon its acceptable performance in the inspection phase of the program. The laboratory must take steps to correct the issues cited above. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days of receipt of this correspondence. It is *not necessary* for the laboratory to submit a written response to RTI. 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 Baylor at (919) 541-7043.

Sincerely,



Susan Crumpton
NLCP Inspection Analyst

Enclosure

cc: Project Files/M10



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: LabOne, Inc.

Location: Lenexa, KS

Document Reviewed: Application Form
 Inspection Report #M10 Date: 13 January 2000
 Other _____

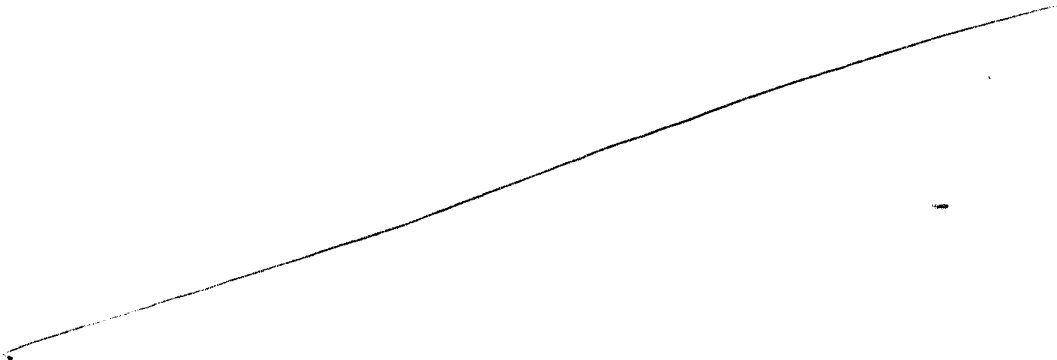
Status: Highly Acceptable Acceptable
 Unacceptable Failure

A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

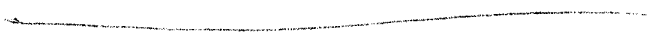
There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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

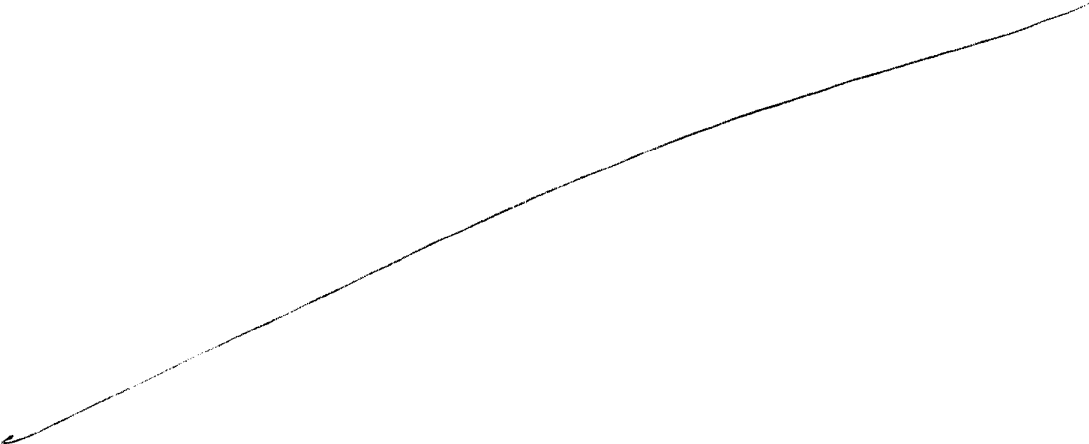
Section E. Standard Operating Procedures - Procedures Manual



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



Section G. Quality Control



Section H. Initial Tests

Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

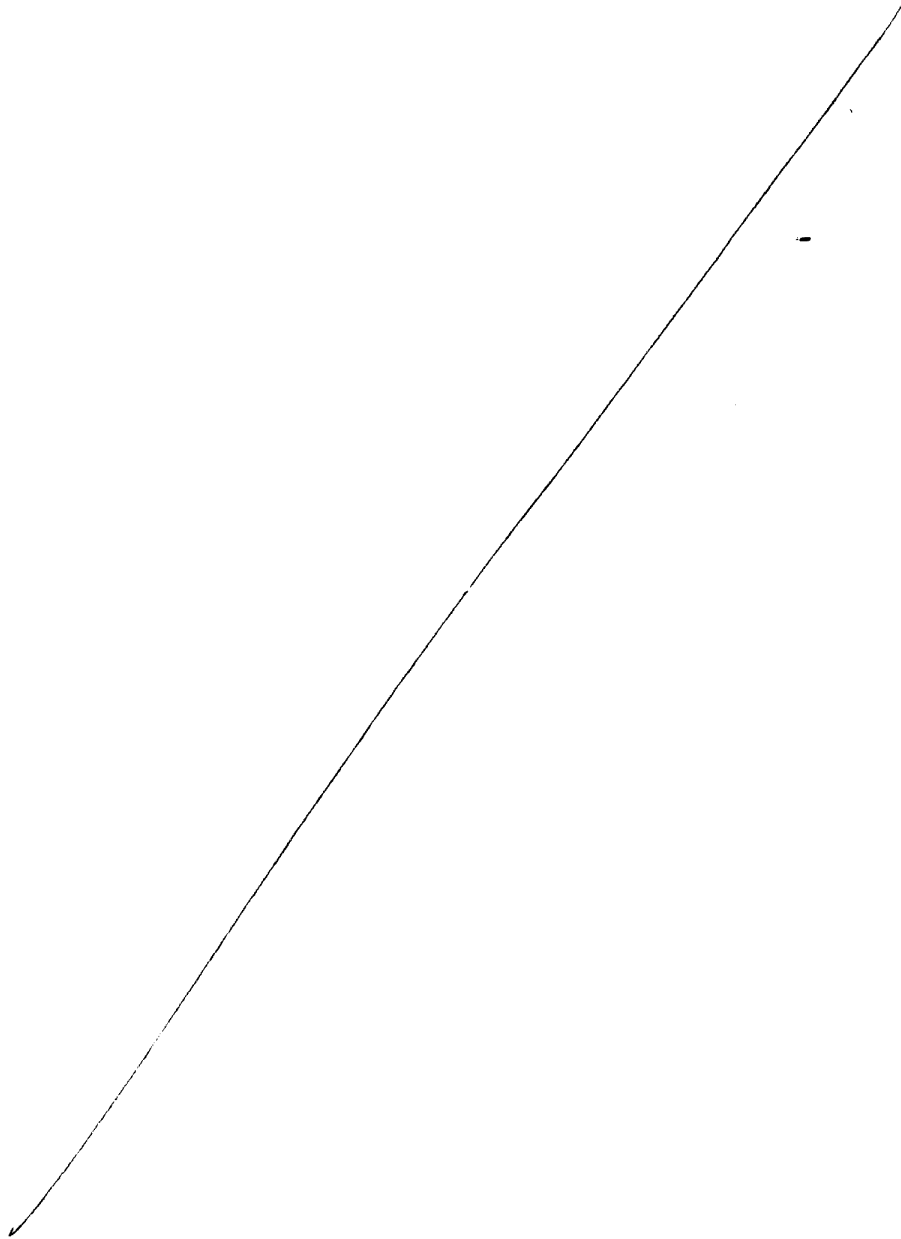
November 17, 2000

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

Dear Dr. Peat:

The enclosed critique was developed from the inspection reports of the inspectors who conducted the eleventh maintenance inspection of your laboratory under the National Laboratory Certification Program (NLCP). Based upon our review of these reports, the laboratory's performance in this inspection is highly acceptable. The inspection team had some areas of concern, which are detailed in this cover letter and attached critique.



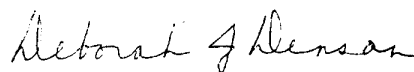


Dr. Peat
November 17, 2000
Page 3 of 3

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. Once these issues have been successfully addressed, RTI will recommend to the Department of Health and Human Services (HHS) that the laboratory's certification be continued. 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson
NLCP Technical Analyst

Enclosure
cc: Project Files/M11



NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

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

Laboratory: LabOne, Inc.

Location: Lenexa, KS

Document Reviewed: Application Form
 Inspection Report #M11 Date: 20 July 2000
 Other _____

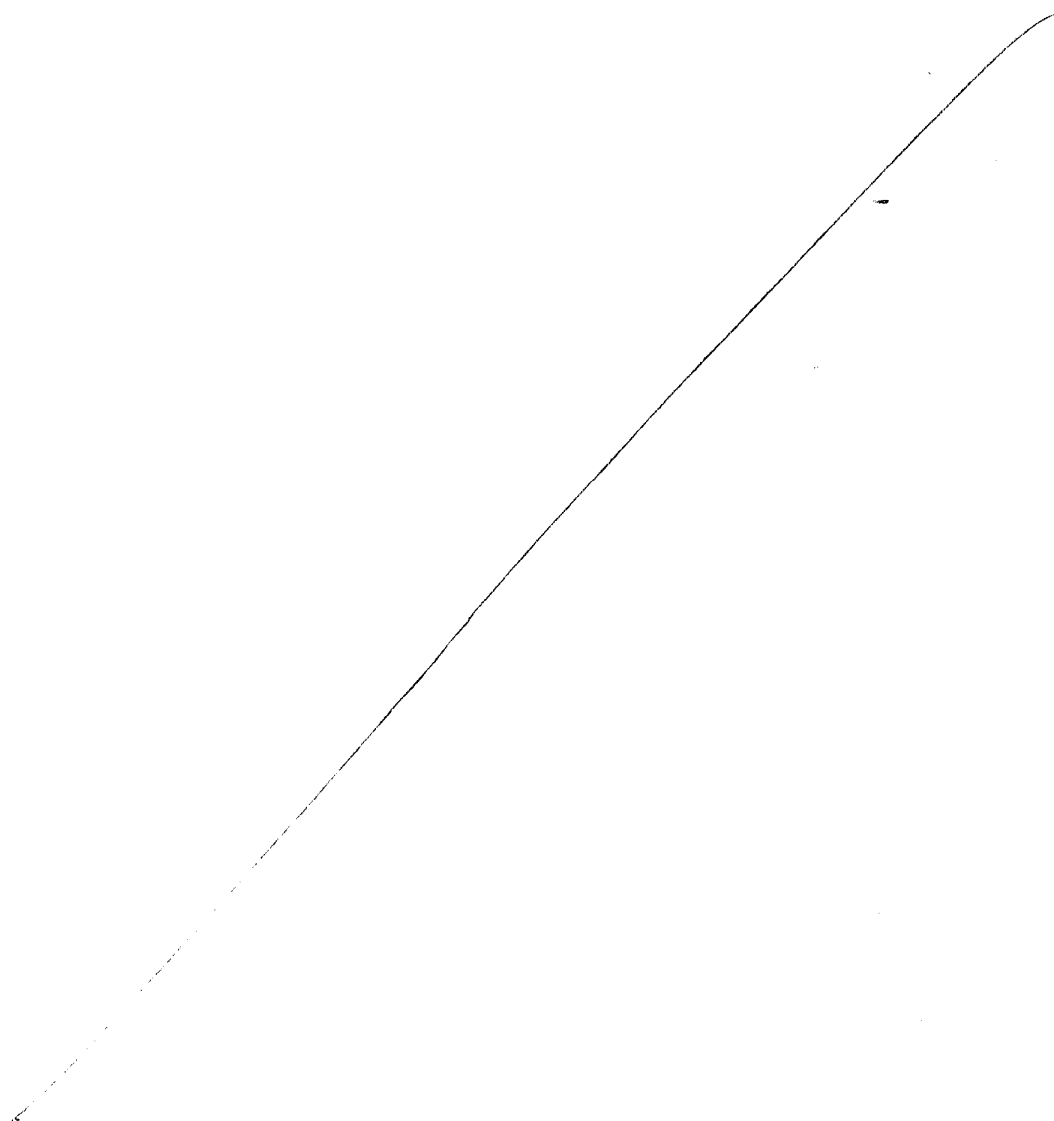
Status: Highly Acceptable Acceptable
 Unacceptable Failure

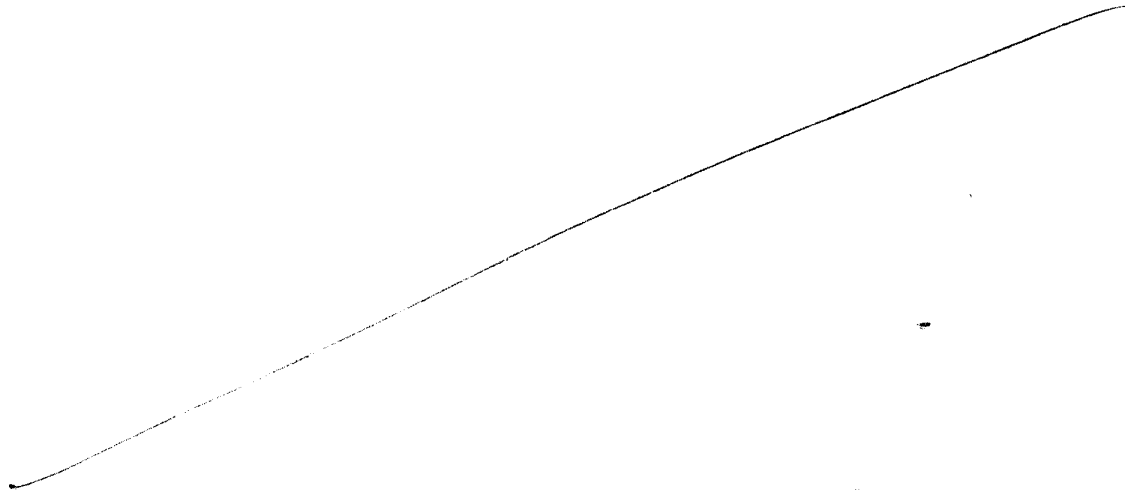
A review of the National Laboratory Certification Program (NLCP) inspection reports has been completed. It is the judgment of the reviewers that the laboratory has met the standards required for the inspection phase of the Program.

There were a number of comments and observations generated as a result of the inspection that are detailed on the following pages for the attention of the laboratory before its next inspection.

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





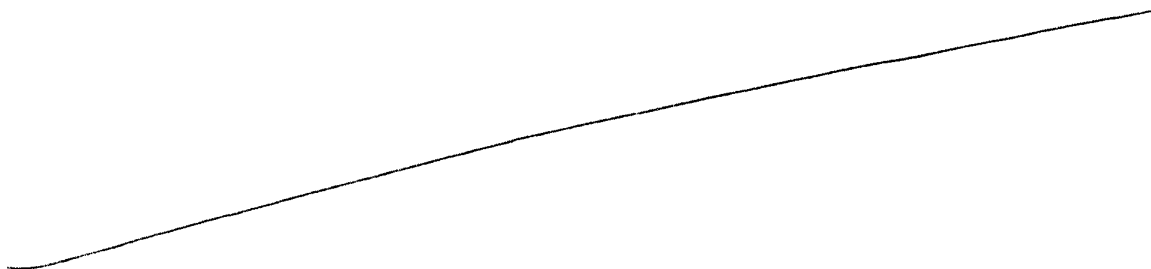
Section F. Chain-of-Custody, Accessioning, and Security



Section G. Quality Control



Section H. Initial Tests



Section I. Confirmatory Tests

Section J. Records Audit

Section K. Reporting

Section L. Computers, Software, and LIMS

Section M. Equipment and Maintenance

Section N. Personnel



received
12/28/00 DD

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

December 26, 2000

Ms. Deborah J. Denson
NLCP Technical Analyst
Research Triangle Institute
National Laboratory Certification Program
3040 Cornwallis Road
PO Box 12194
Research Triangle Park
NC 27709-2194

Re: Laboratory # 0325, Maintenance Inspection #11

Dear Ms. Denson

If any further action is necessary, please contact me at 913-577-1626 or Dawn Hahn at 913-577-1632.

Sincerely,

Lance C. Presley
Responsible Person

RESEARCH TRIANGLE INSTITUTE



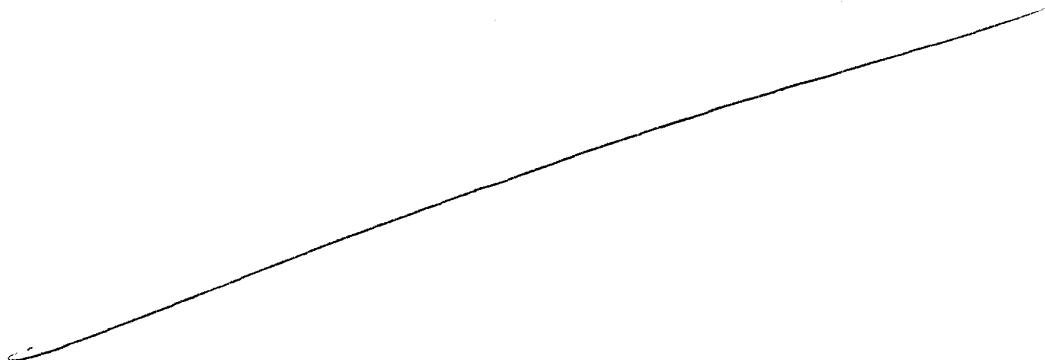
National Laboratory Certification Program

January 8, 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 26, 2000 submitted in response to issues raised during the eleventh maintenance 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 is a review of the material submitted:



Based upon our review of the material submitted, RTI is recommending to the Department of Health and Human Services (HHS) that your laboratory continues to be certified under the National Laboratory Certification Program. All corrective actions must be implemented within 30 days of the receipt of this correspondence and 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) 541-7265 or Michael R. Baylor, Ph.D. at (919) 541-7043.

Sincerely,


Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/M11



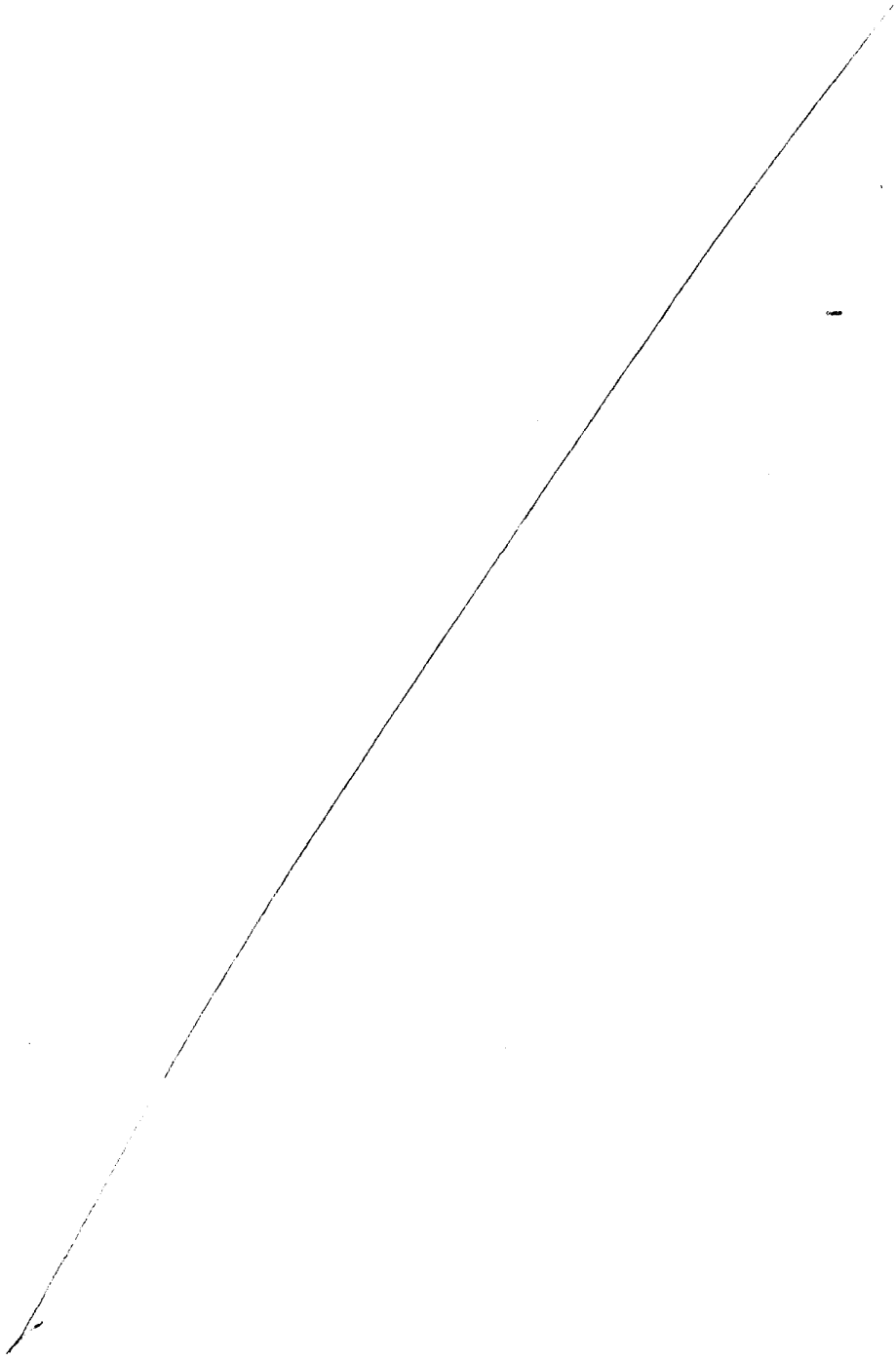
DRAFT

Date: 26 September 2000

Subject : _____

DRAFT

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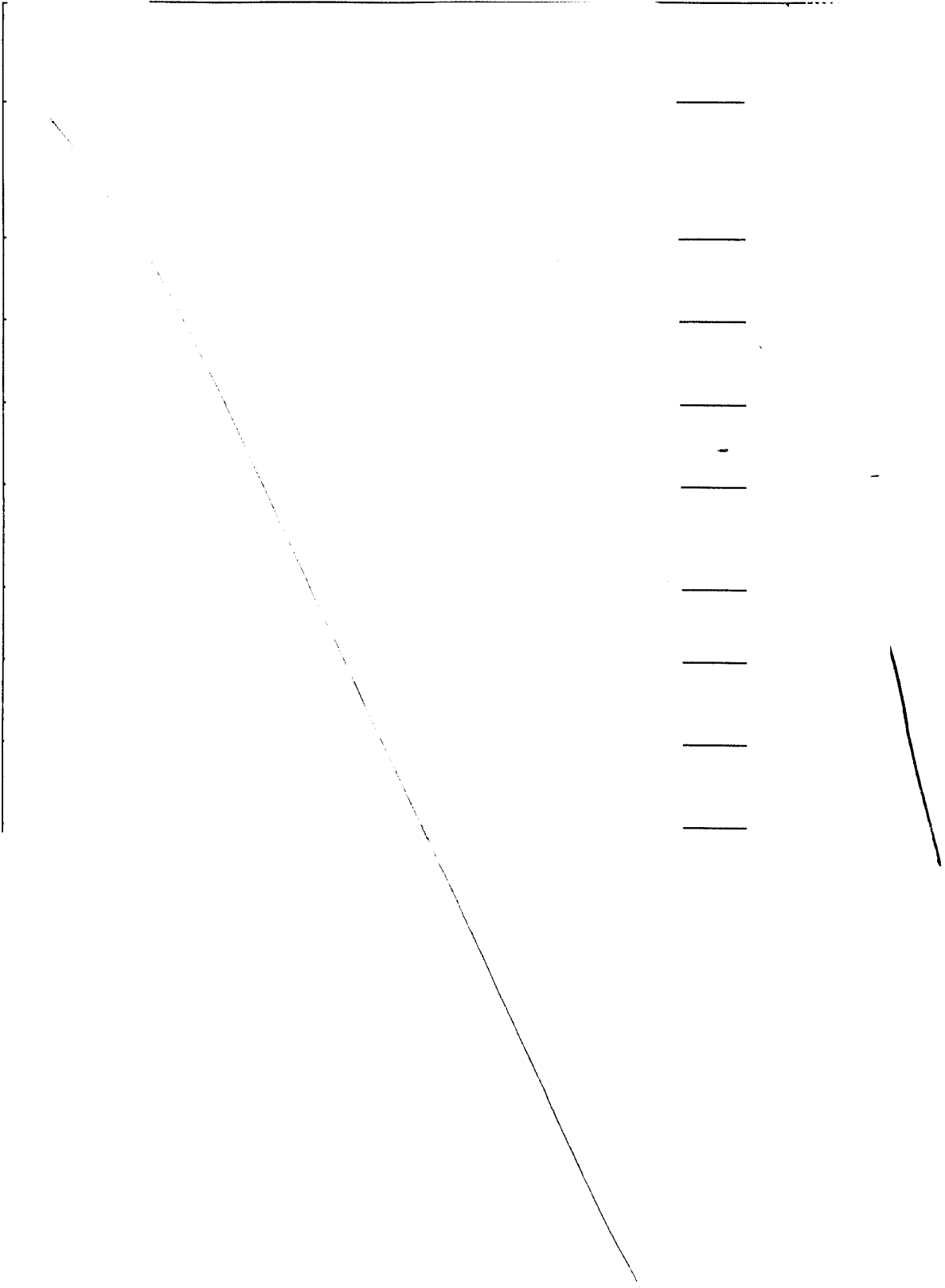
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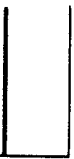
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9-29-00

1 of 2

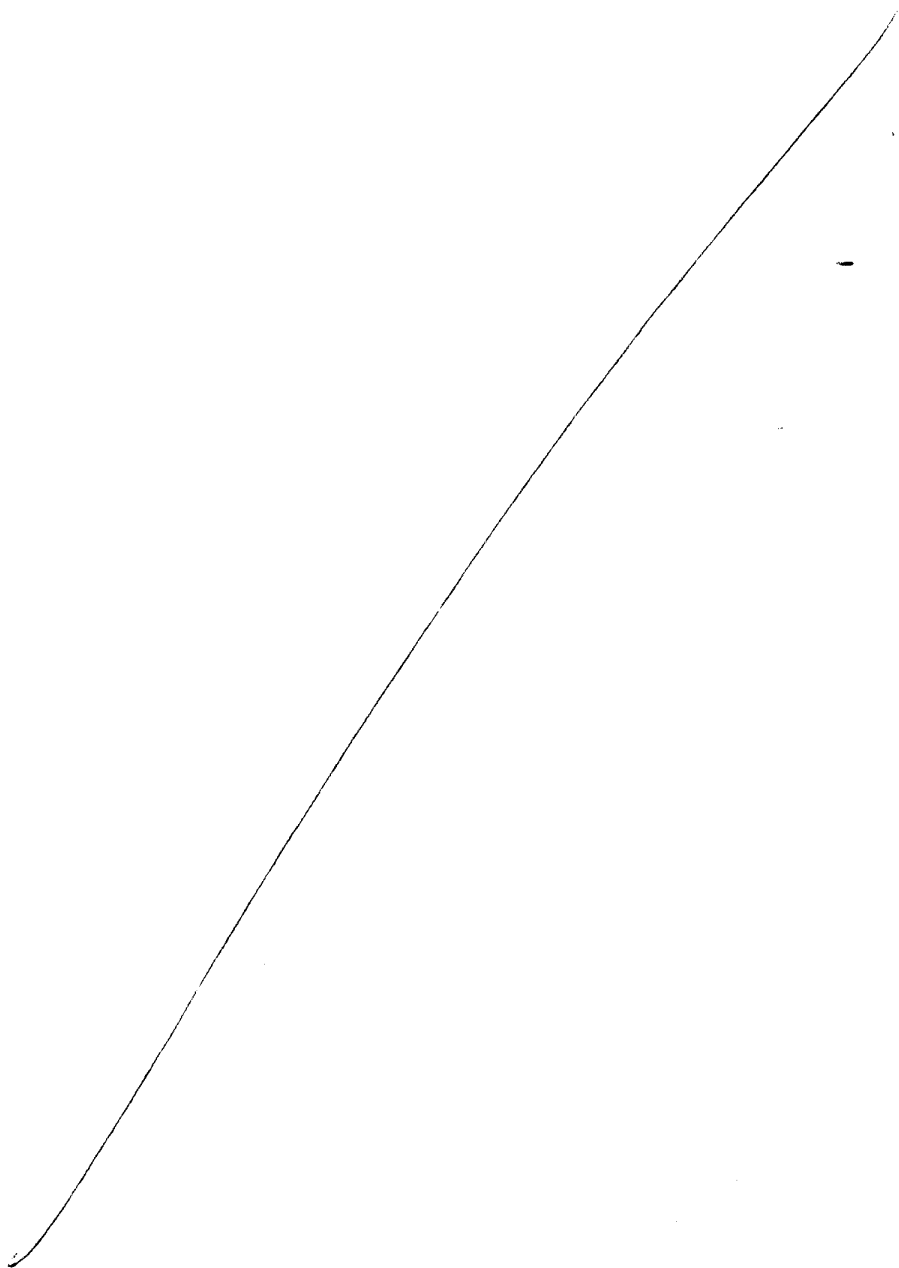
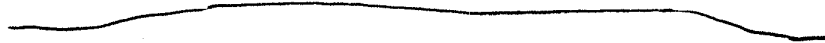




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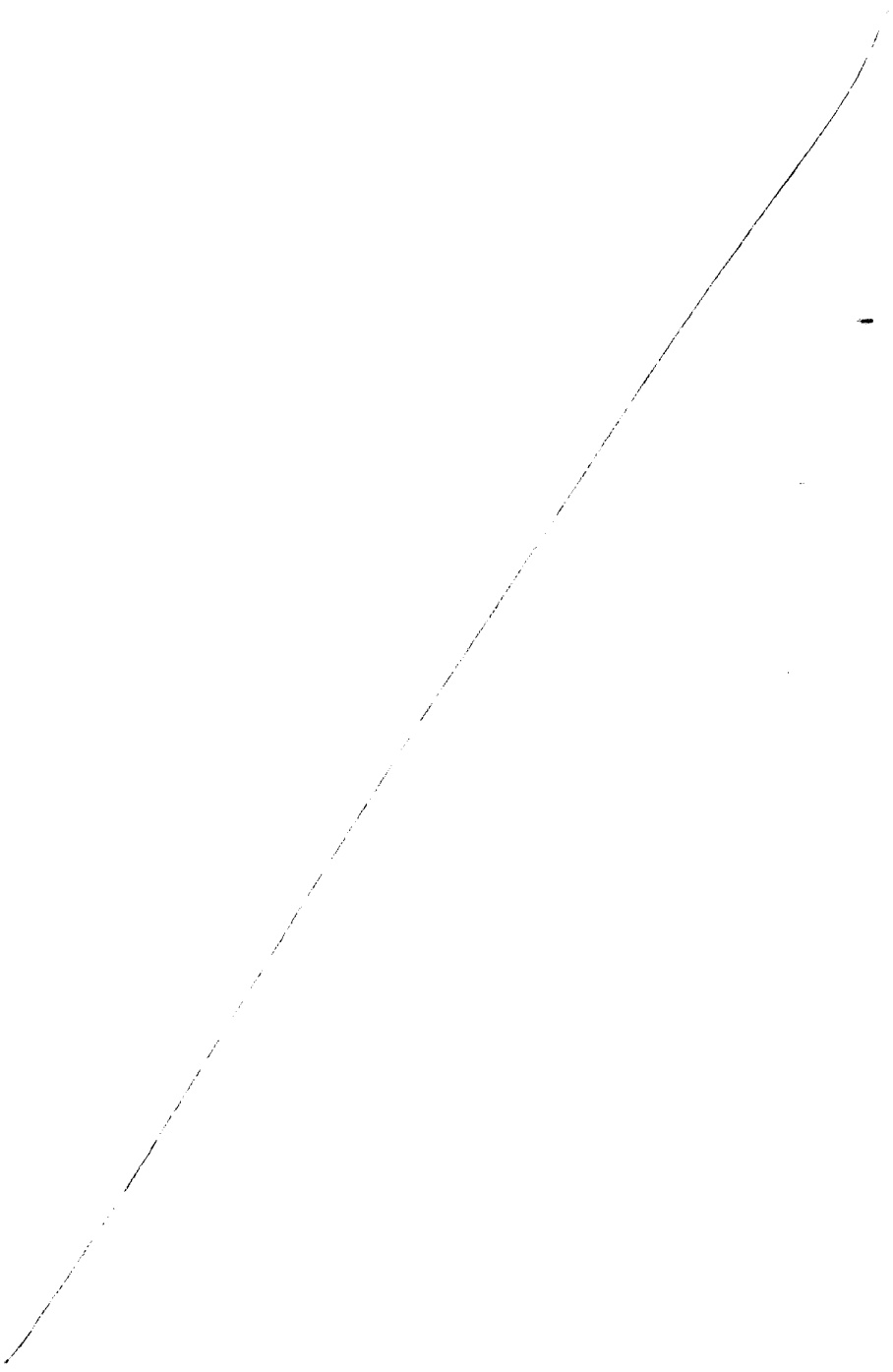
Date: 17 October 2000

Subject:



DRAFT

DRAFT



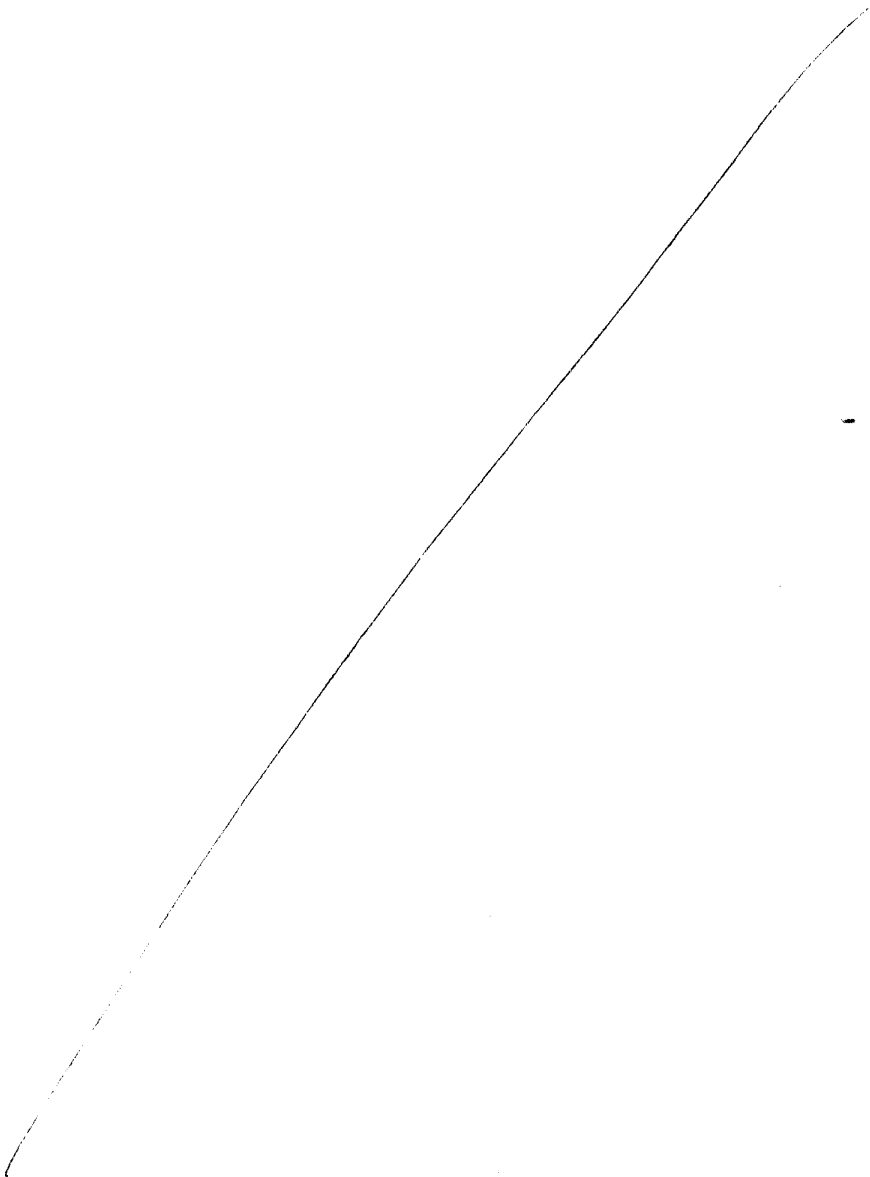
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DRAFT



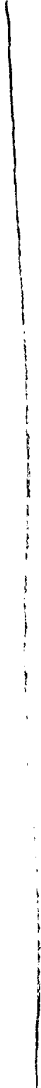
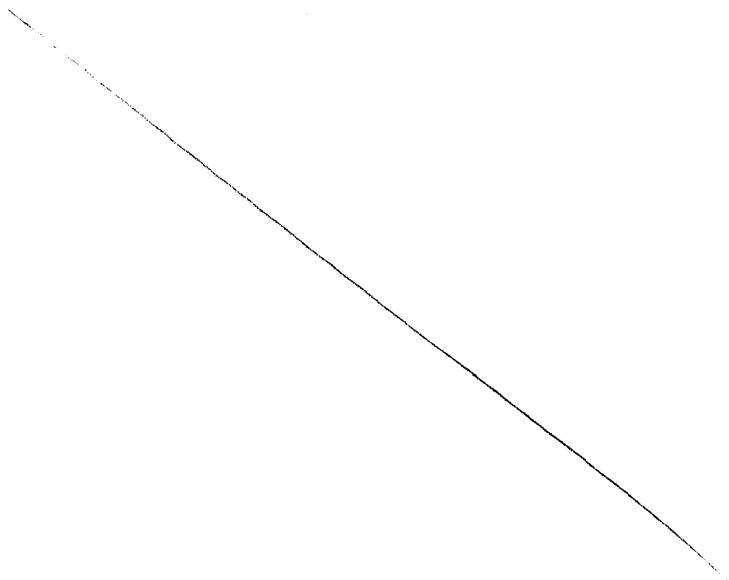
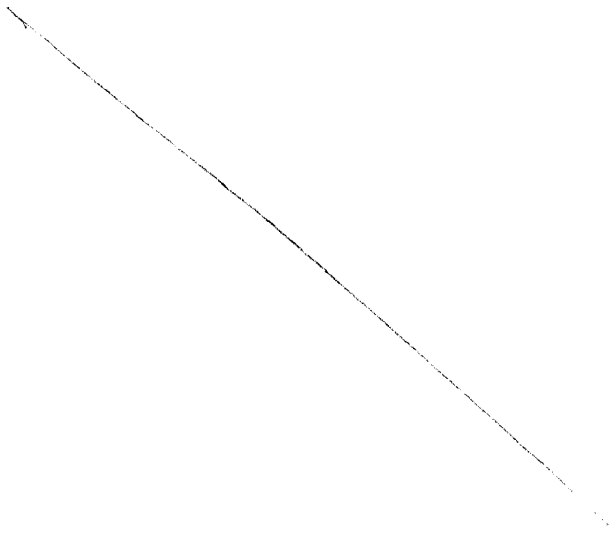
DRAFT

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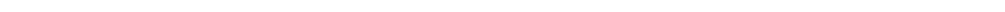
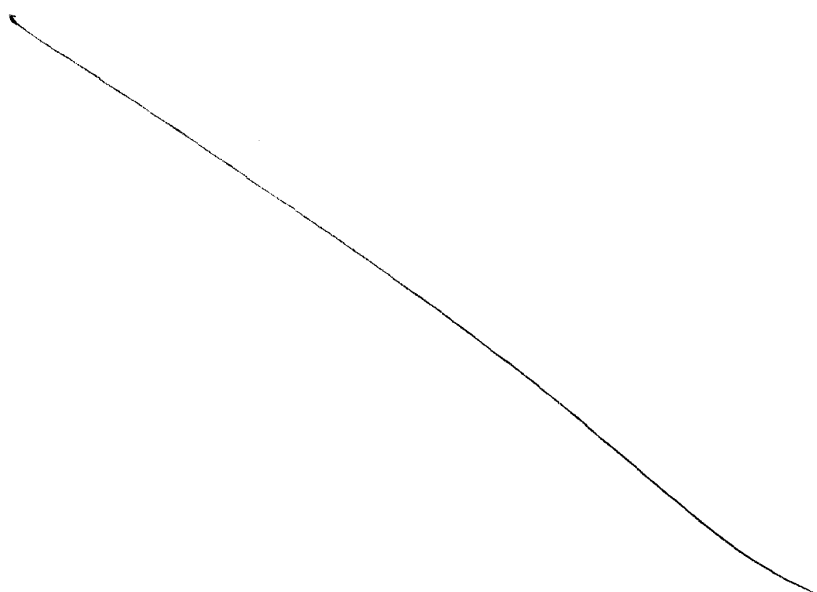
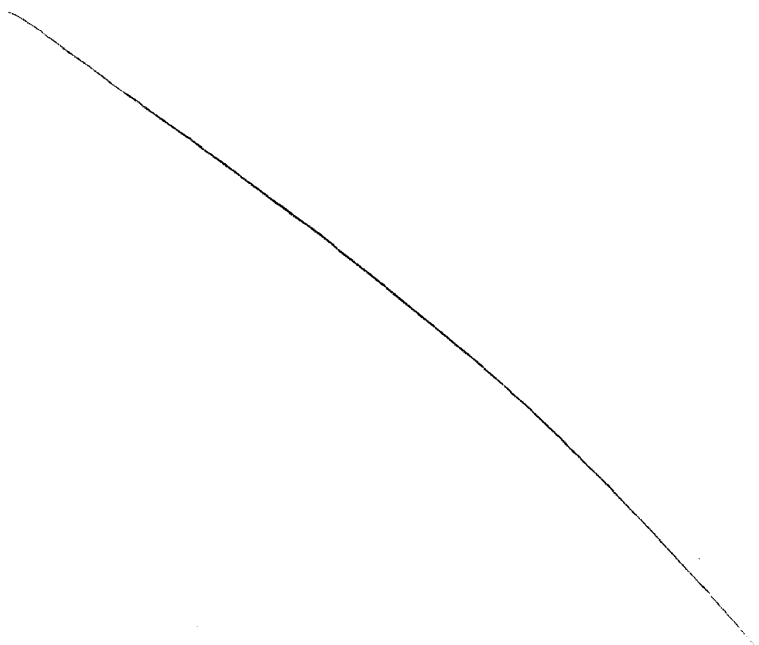


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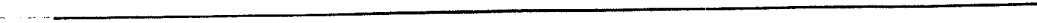
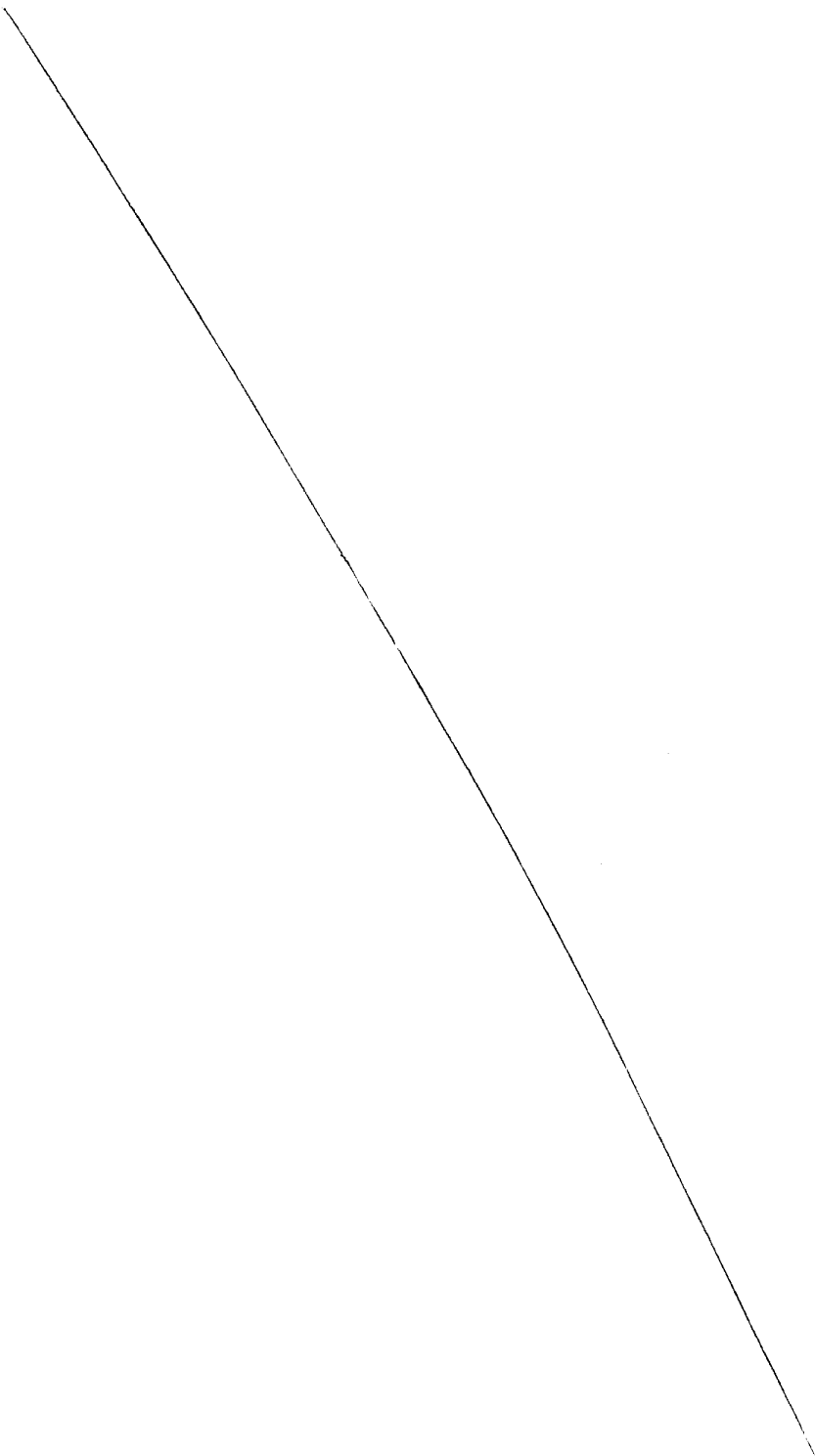
14/10



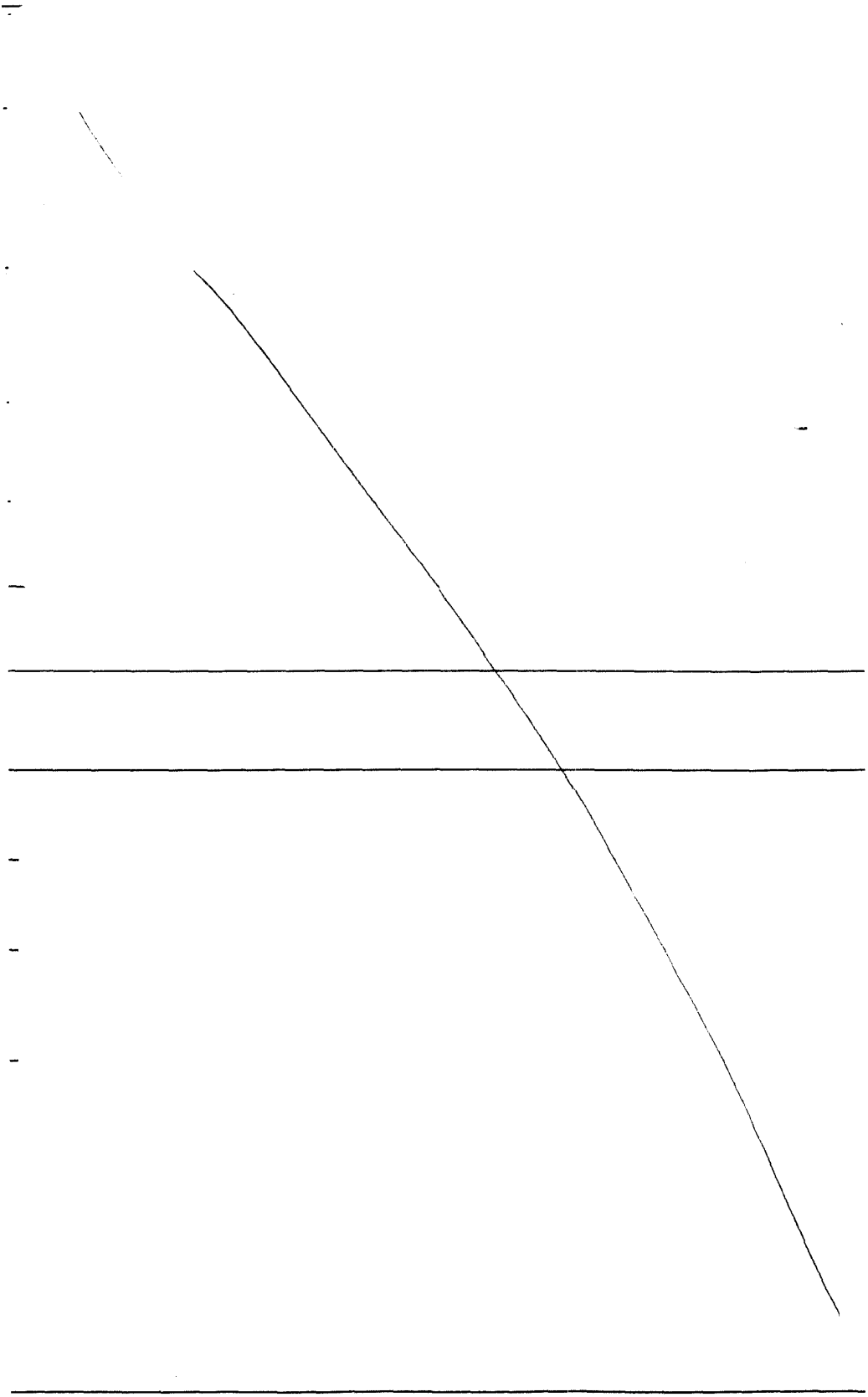
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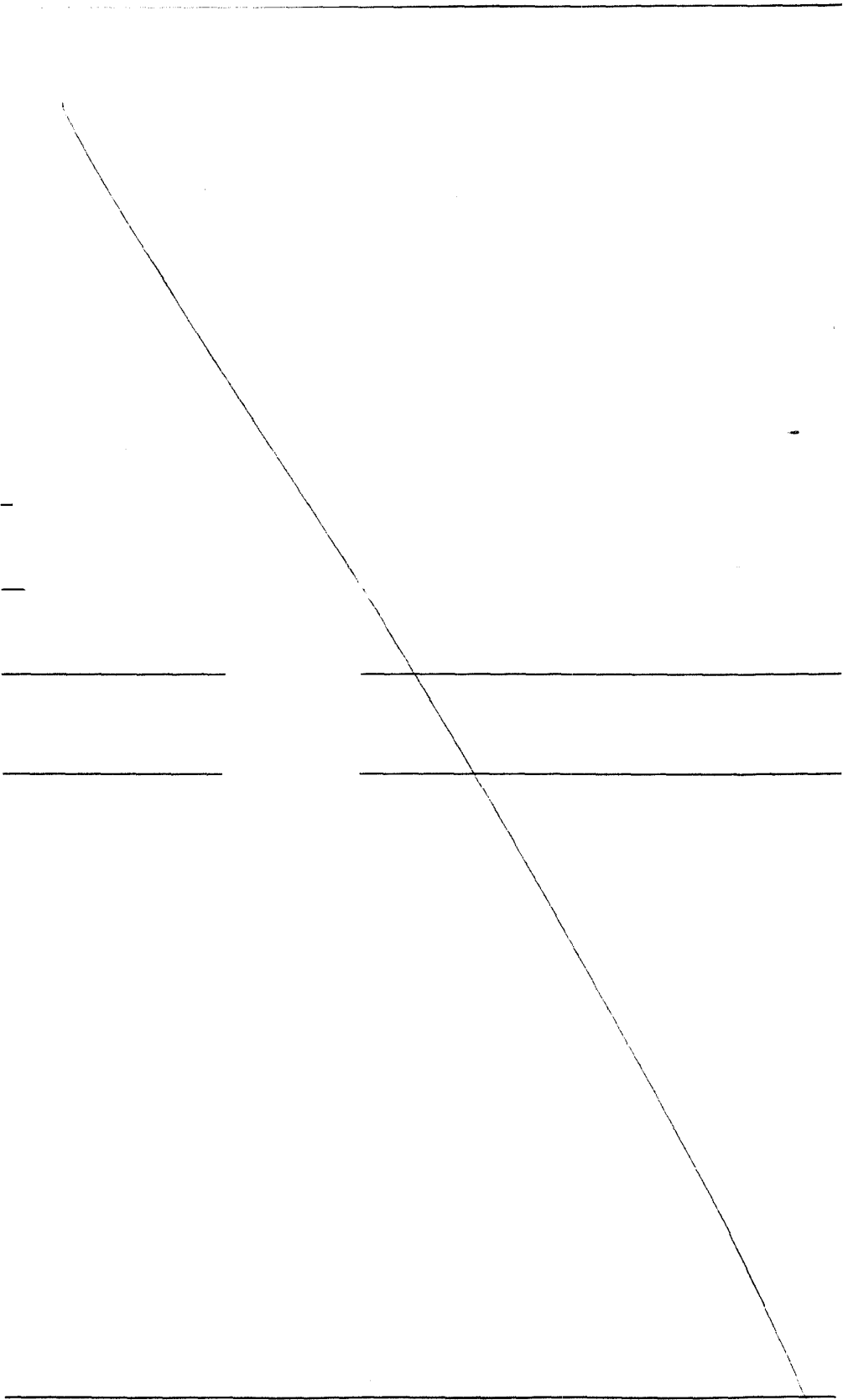
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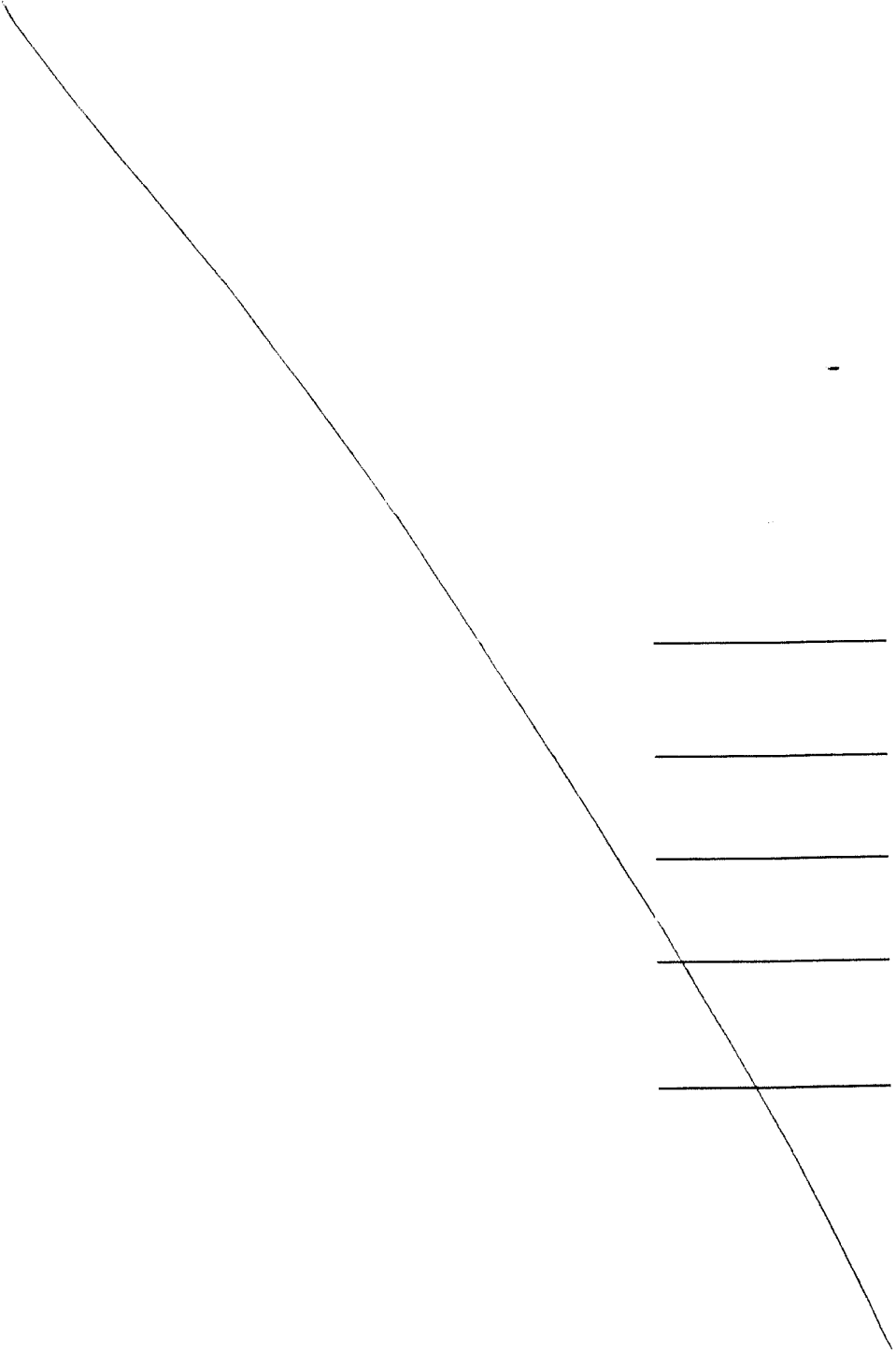
49/10



5910

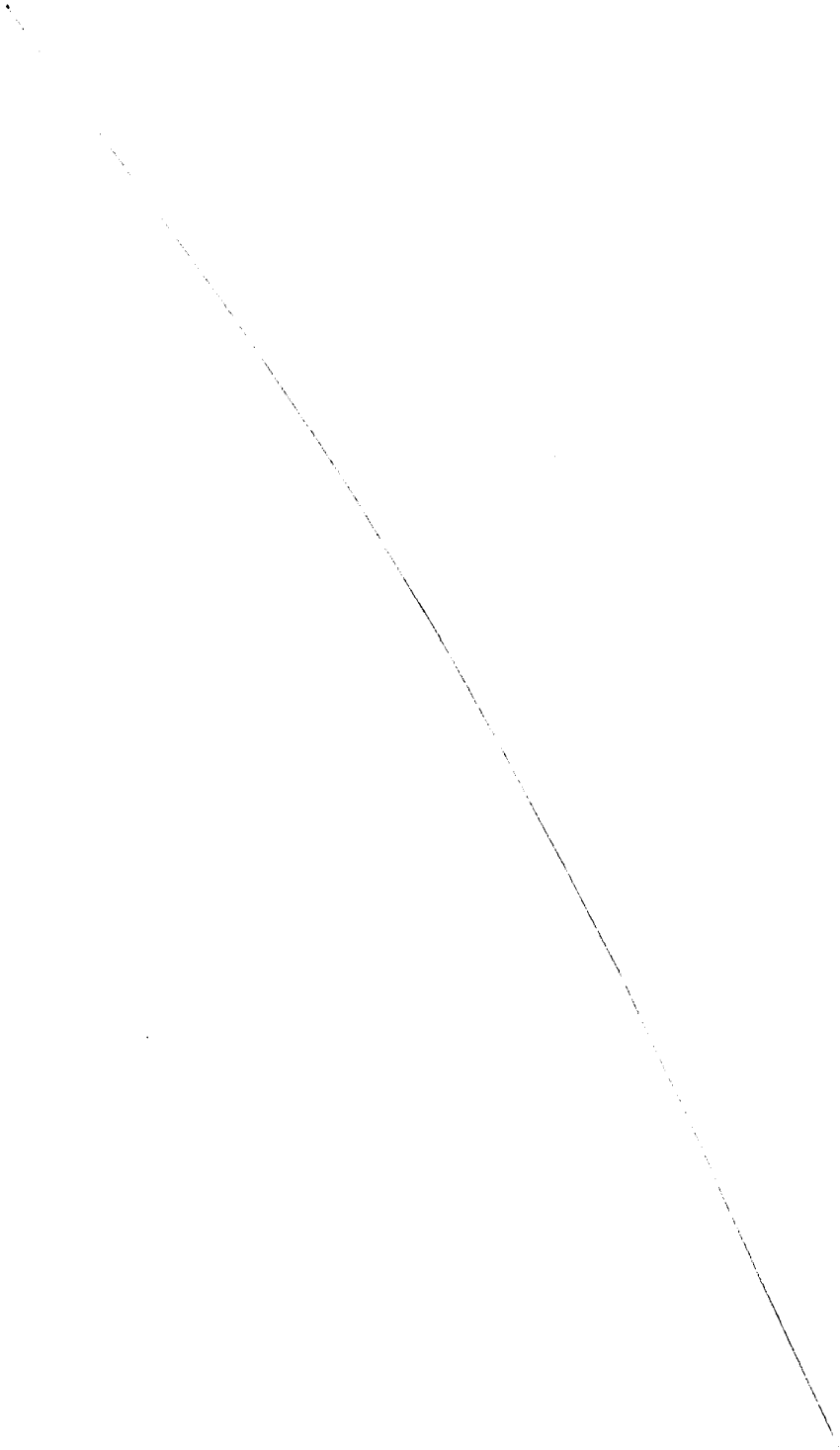


6 of 10

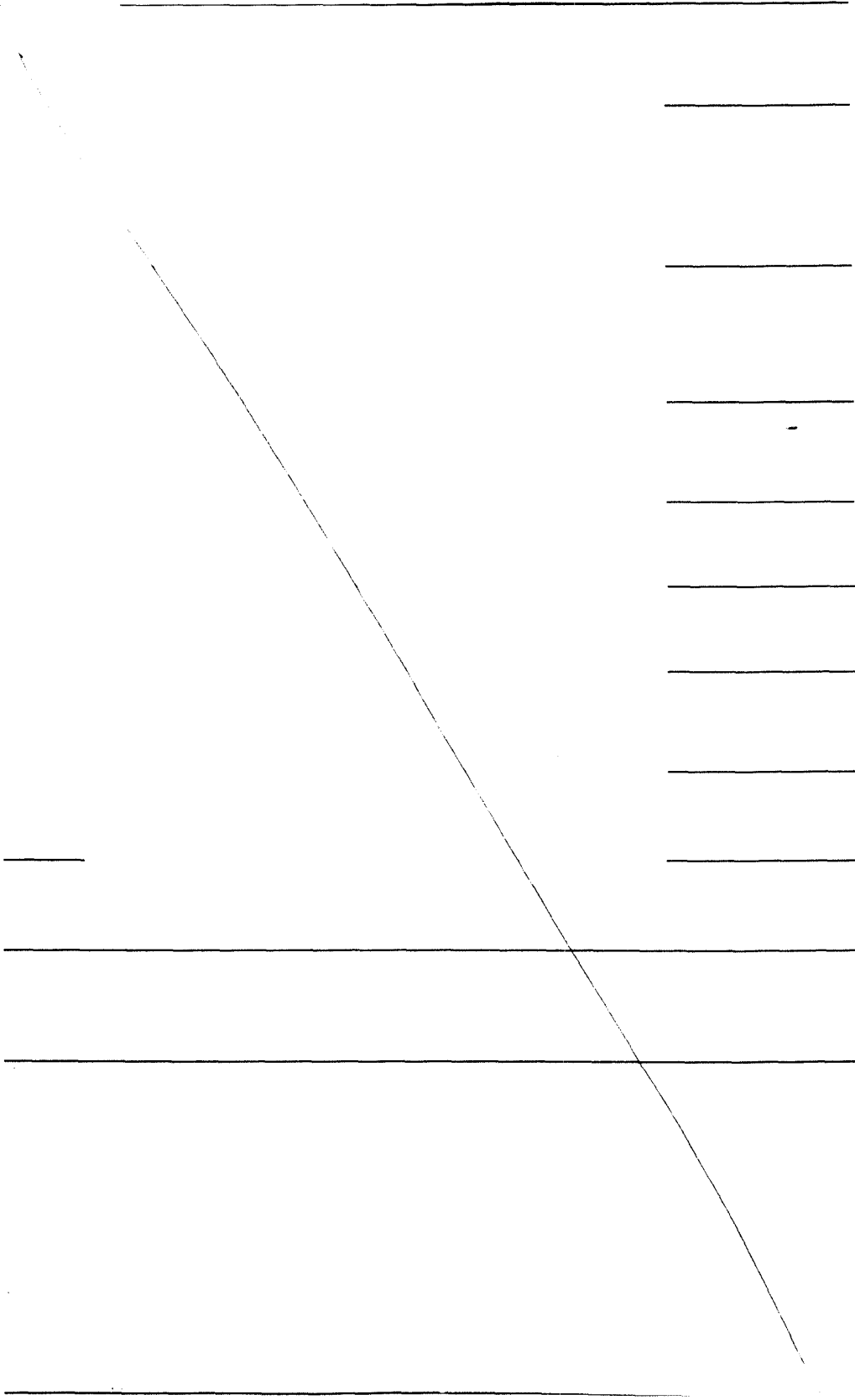


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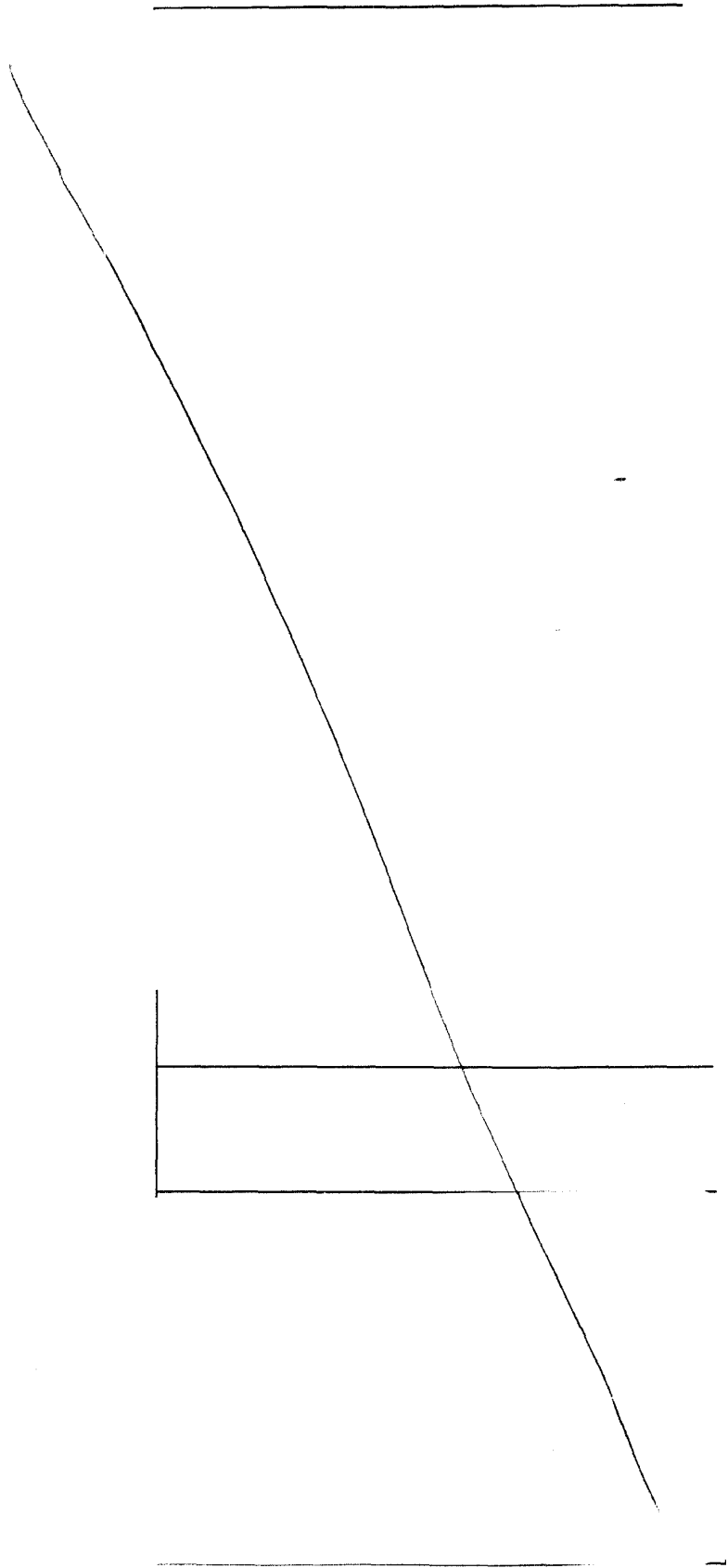


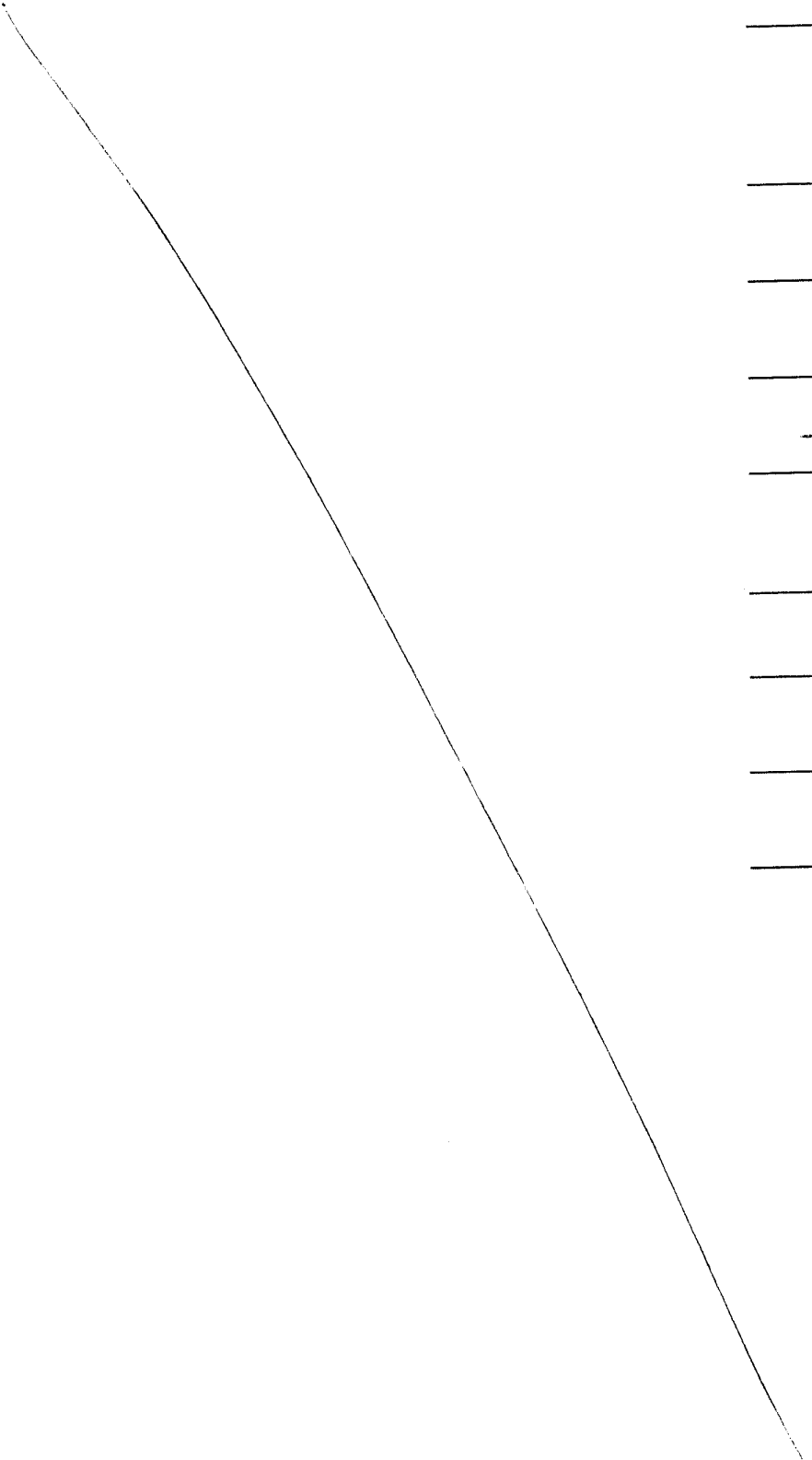
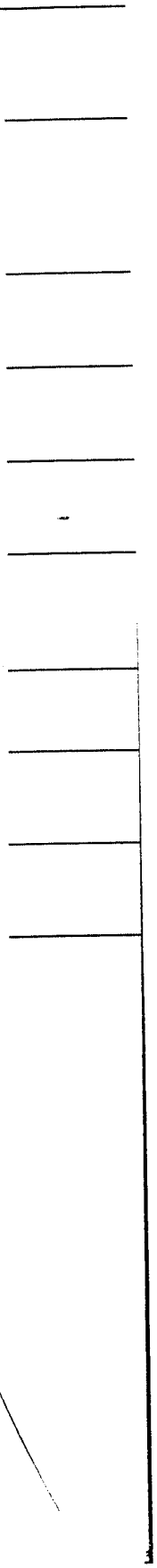
01 Feb



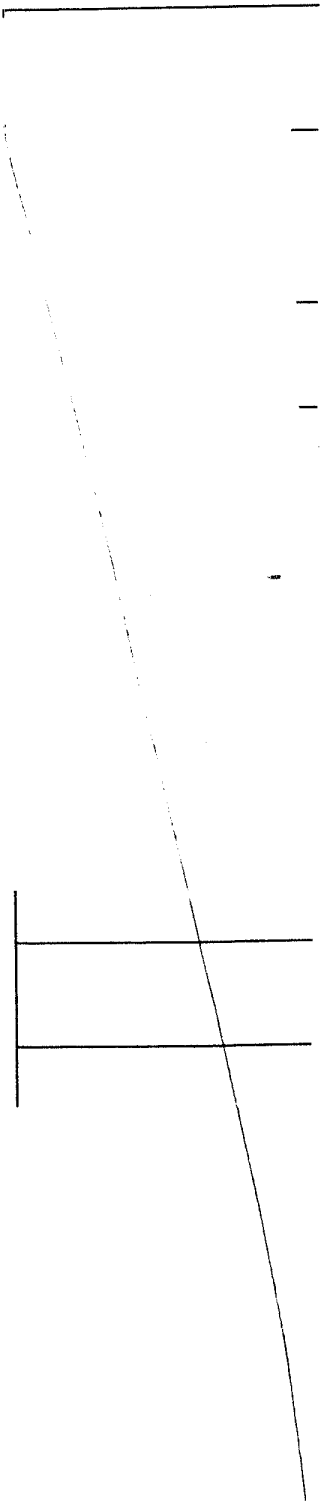
01 Feb 6

10 4/10





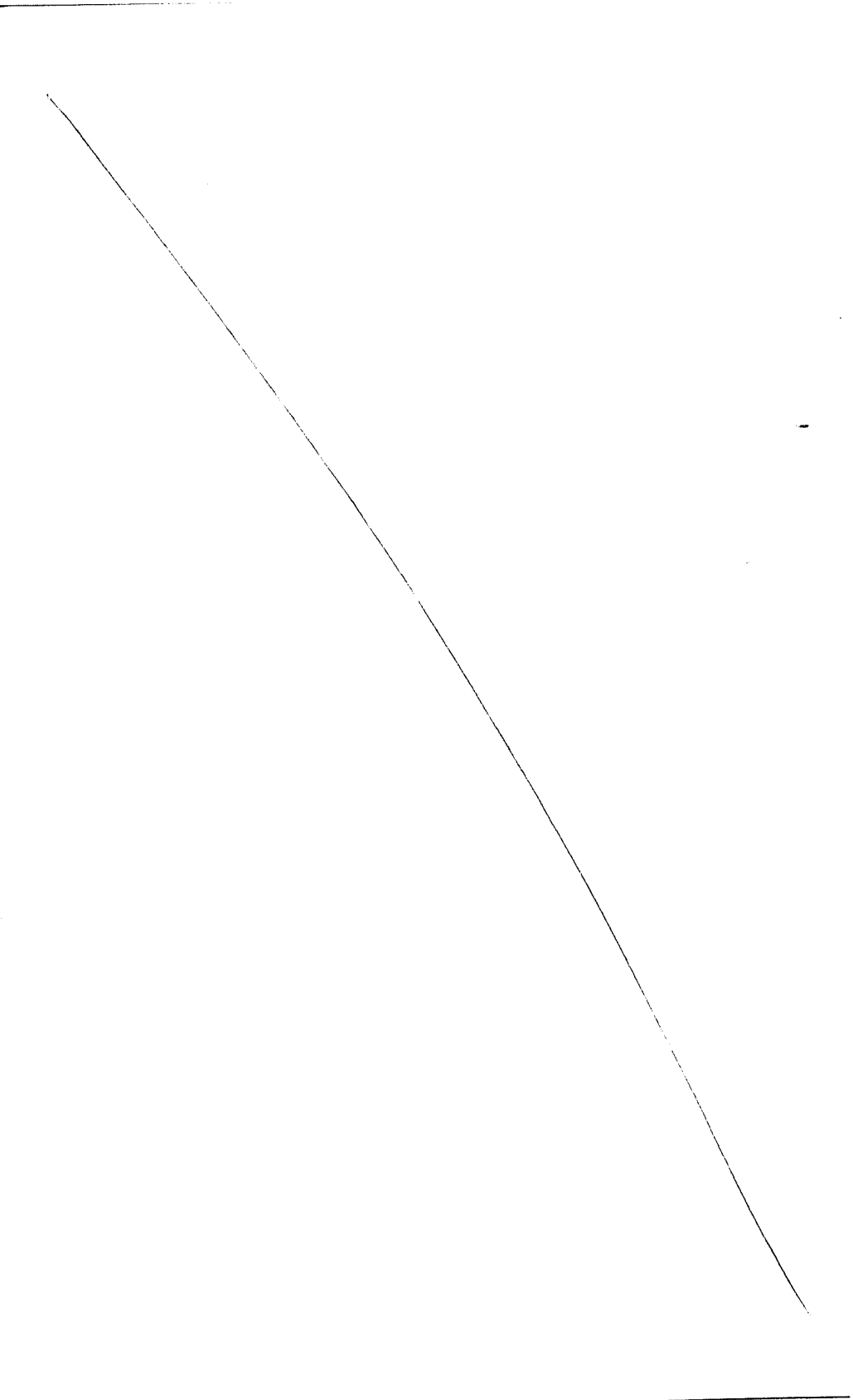
9-29-00



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9-29-00

1 of 3



9-29-00

2 of 3

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