

## Validity Testing Information Part I

Laboratory Name: ALABAMA REFERENCE LABORATORIES / LABSOUTH  
Address: PO BOX 4600, 543 S. HULL ST., MONTGOMERY, AL 36103-4600  
Responsible Person: DR. C. THOMAS HUBER (Printed Name)

Per Allen Valen  
10/5/00

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).

*Allen Vaara (ALT. Rep)*  
Signature, Responsible Person

10-4-00  
Date

ALLEN VAARA  
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).

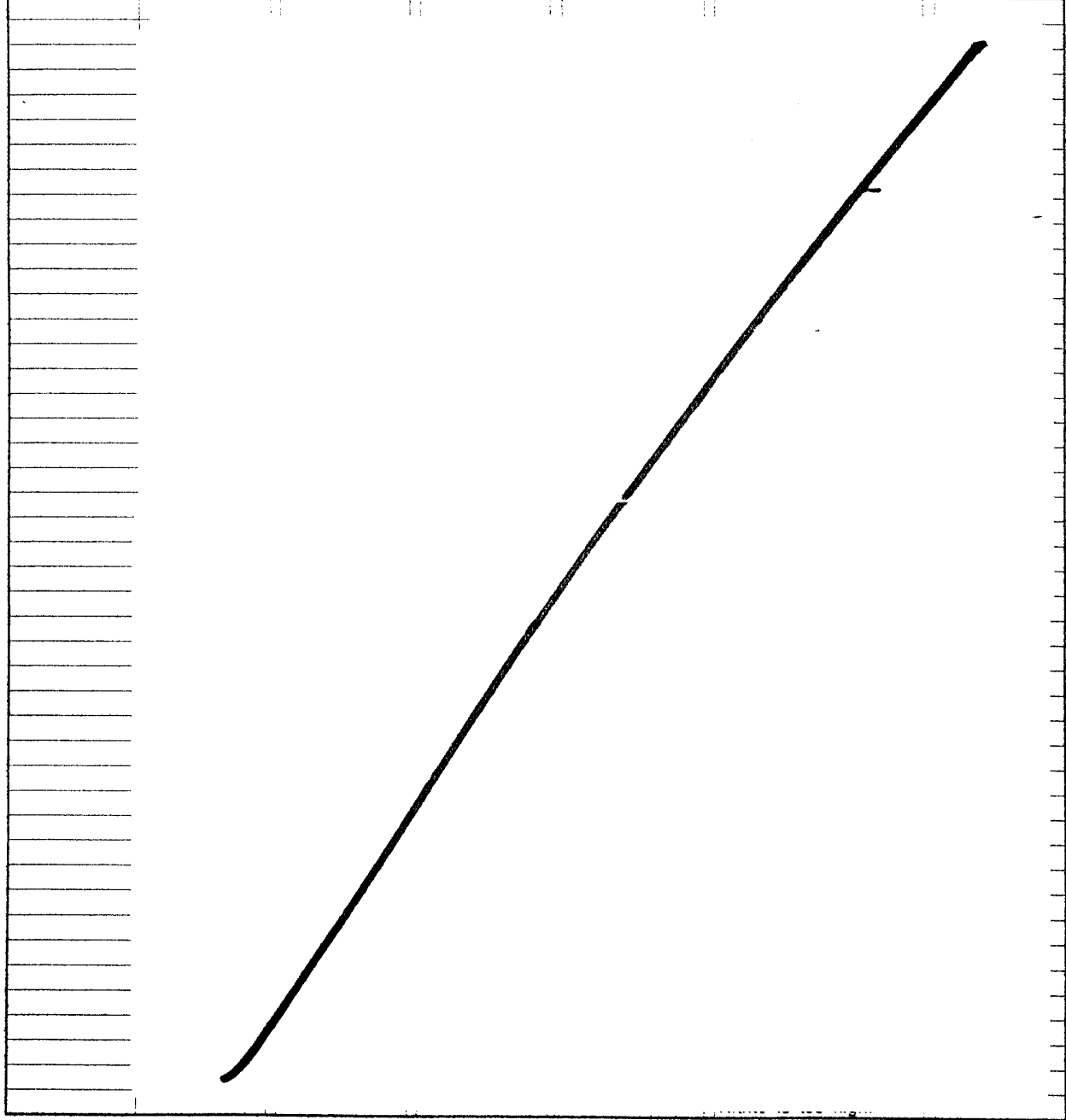
C. Thomas Huber, Ph.D.  
Signature, Responsible Person

10/16/00  
Date

C. Thomas Huber  
Printed Name, Responsible Person

VALIDITY TESTING INFORMATION, PART II  
FROM ALABAMA REFERENCE LABORATORIES  
MONTGOMERY, ALABAMA

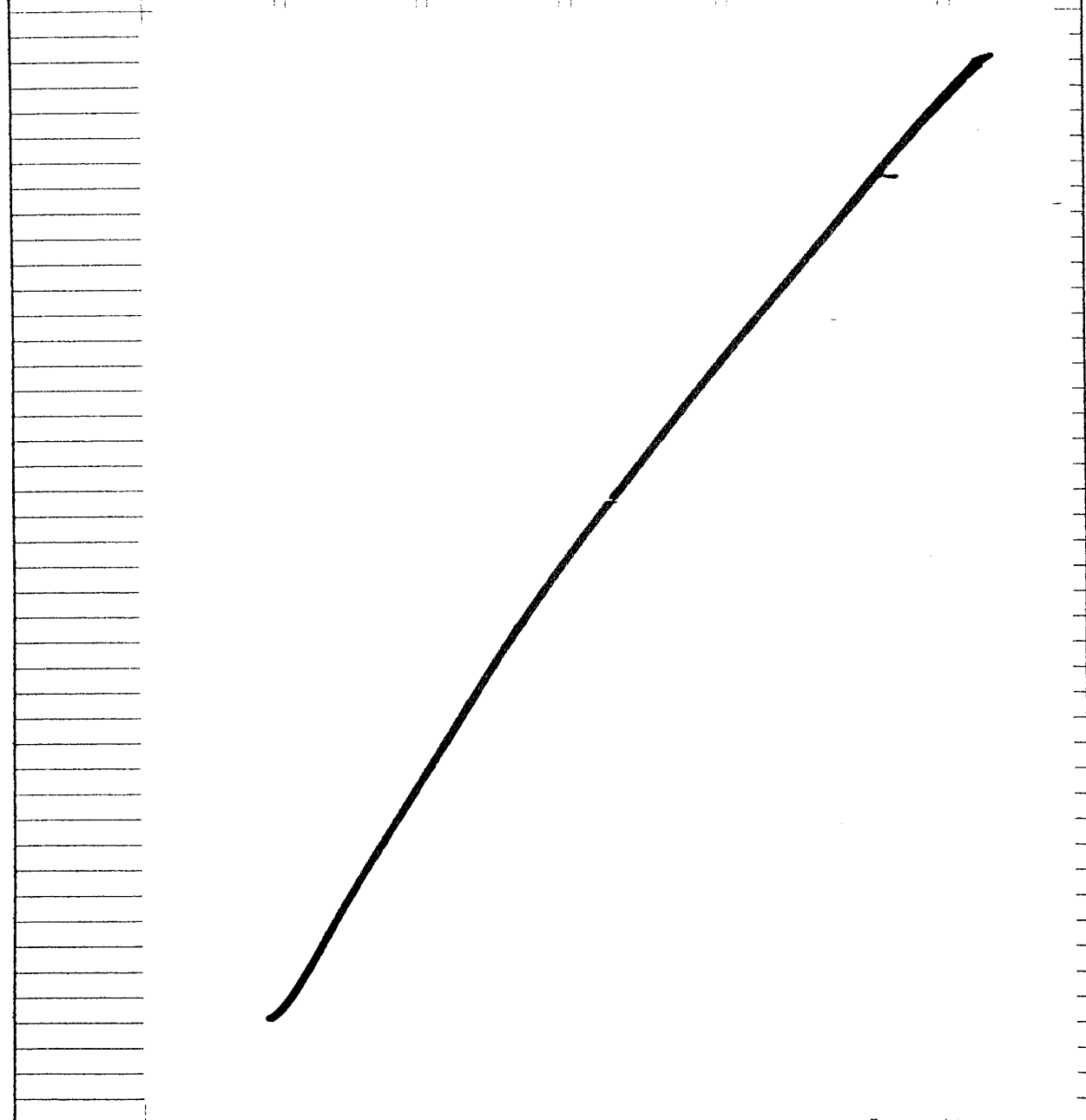
SPEC. ID #	ACCESSION #	DATE REC'D	DATE REPORTED	REPORTED RESULT	QUANTITATIVE RESULT FOR NITRITE
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*C. Thomas Huber*  
10/16/00

VALIDITY TESTING INFORMATION, PART II  
 FROM ALABAMA REFERENCE LABORATORIES  
 MONTGOMERY, ALABAMA

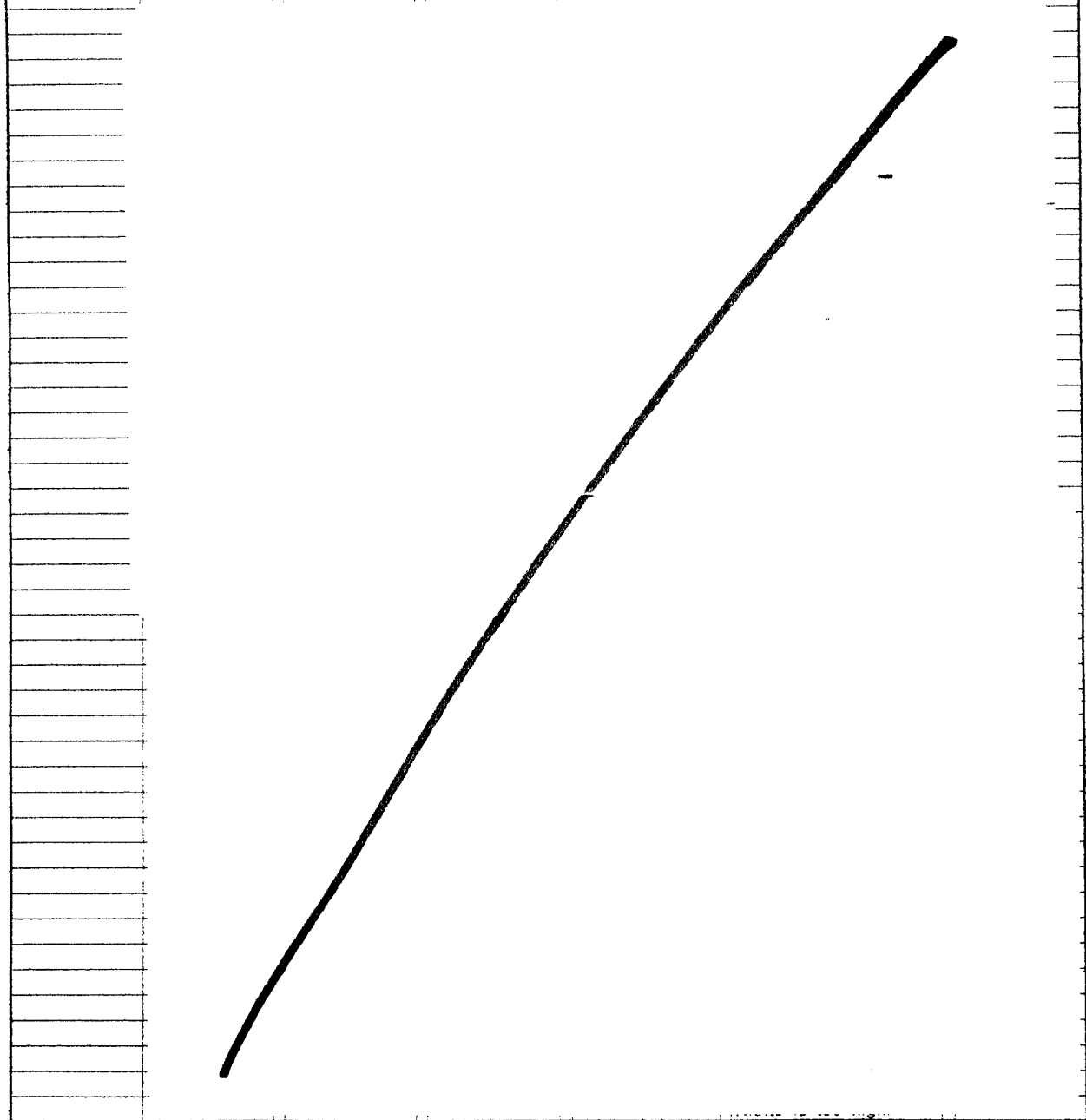
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*C. Thomas Huber*  
 10/16/00

VALIDITY TESTING INFORMATION, PART II  
FROM ALABAMA REFERENCE LABORATORIES  
MONTGOMERY, ALABAMA

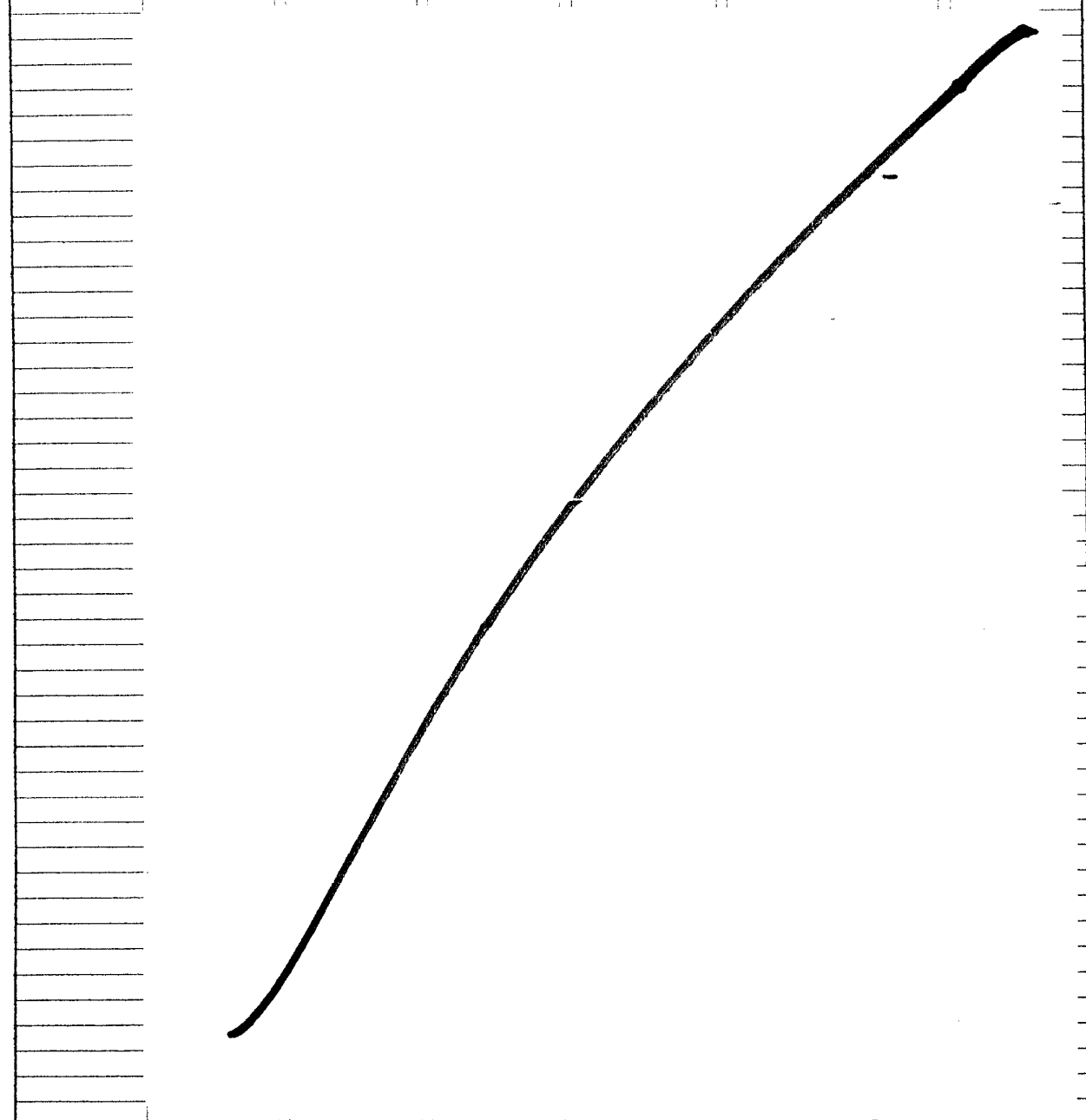
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*C. Thomas Huber*  
10/16/82

VALIDITY TESTING INFORMATION, PART II  
 FROM ALABAMA REFERENCE LABORATORIES  
 MONTGOMERY, ALABAMA

SPEC. ID #	ACCESSION #	DATE RECVD	DATE REPORTED	REPORTED RESULT	QUANTITATIVE RESULT FOR NITRITE
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*C. Thomas / fuber*  
 10/16/03

VALIDITY TESTING INFORMATION, PART II  
 FROM ALABAMA REFERENCE LABORATORIES  
 MONTGOMERY, ALABAMA

SPEC. ID #	ACCESSION #	DATE REC'D	DATE REPORTED	REPORTED RESULT	QUANTITATIVE RESULT FOR NITRITE
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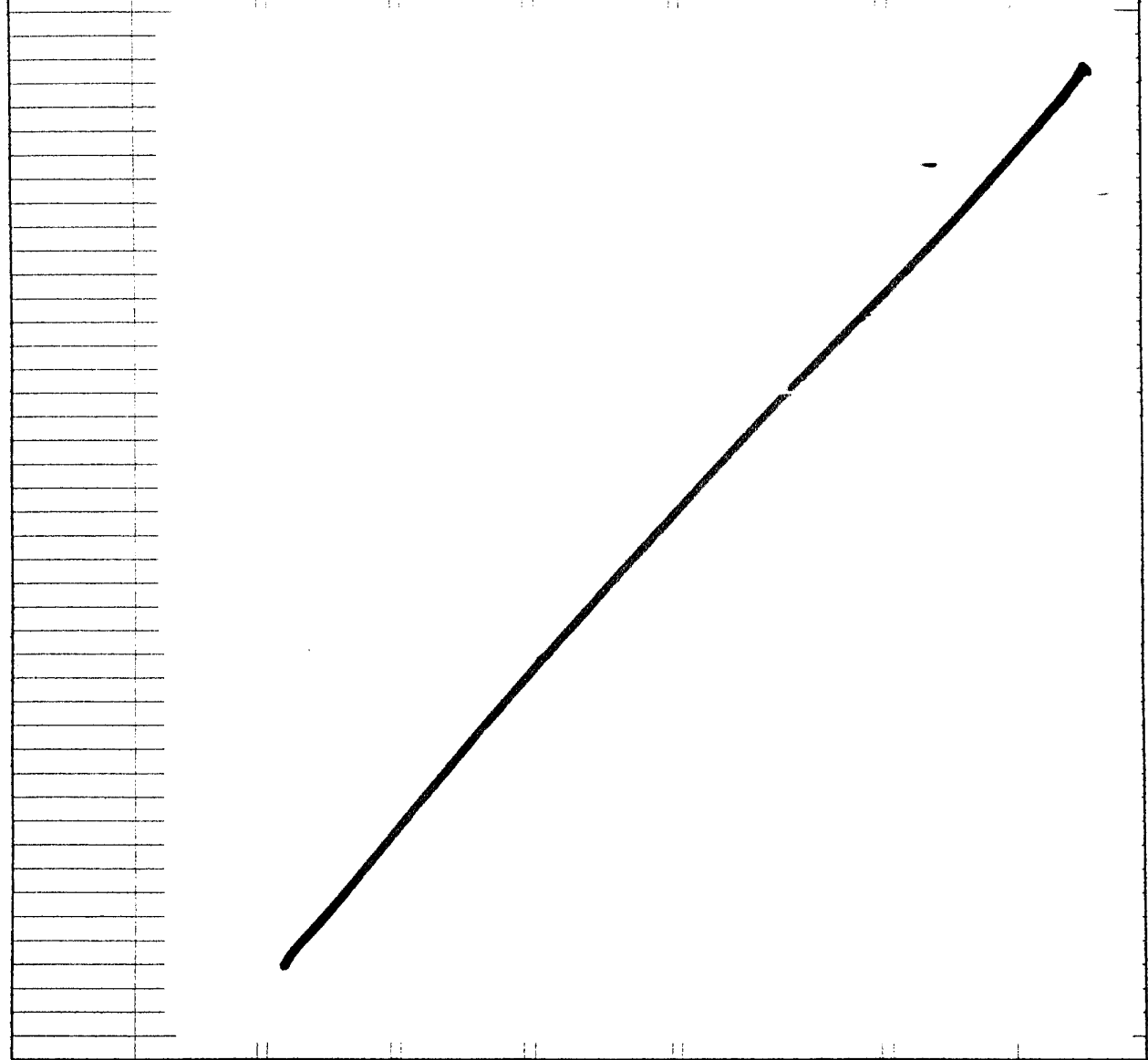


*C. Thomas Huber*  
 10/16/00



VALIDITY TESTING INFORMATION, PART II  
 FROM ALABAMA REFERENCE LABORATORIES  
 MONTGOMERY, ALABAMA

SPEC. ID #	ACCESSION #	DATE RECVD	DATE REPORTED	REPORTED RESULT	QUANTITATIVE	QUANTITATIVE
					RESULT FOR	RESULT FOR
					CREATININE	SPECIFIC GRAV.



*C. Thomas Haber*  
 10/16/00

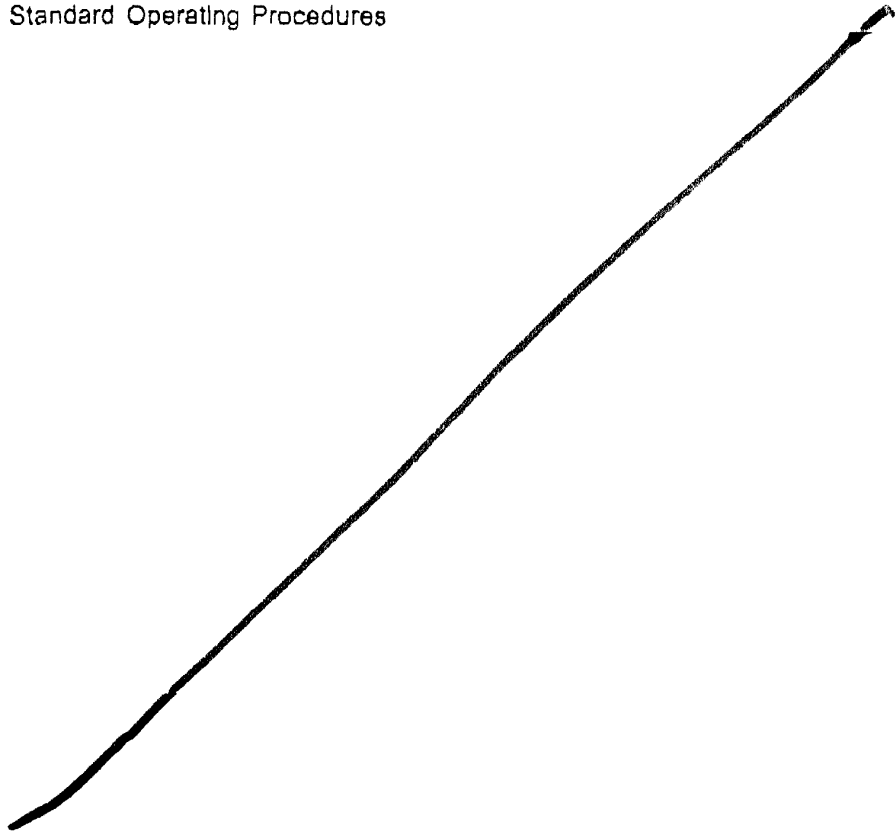
December 27, 2000

0400  
Dr. C. Thomas Huber  
Alabama Reference Laboratories, Inc.  
543 South Hull Street  
Montgomery, AL 36103

Dear Dr. Huber:

The enclosed critique was developed from the inspection report associated with the November 29, 2000 specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in 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:

E2.4. The Standard Operating Procedures



Dr. Huber  
December 27, 2000  
Page 2 of 2

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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 listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. 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. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

*Deborah J. Denson*

Deborah J. Denson  
NLCP Technical Analyst

Enclosure

cc: Project Files/svt400

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## NATIONAL LABORATORY CERTIFICATION PROGRAM

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### Document Review and Critique

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Laboratory I.D. Number: 0400  
Document No. Final

Laboratory: Alabama Reference Laboratories, Inc.

Location: Montgomery, AL

Document Reviewed:  Specimen Validity Testing Inspection Report

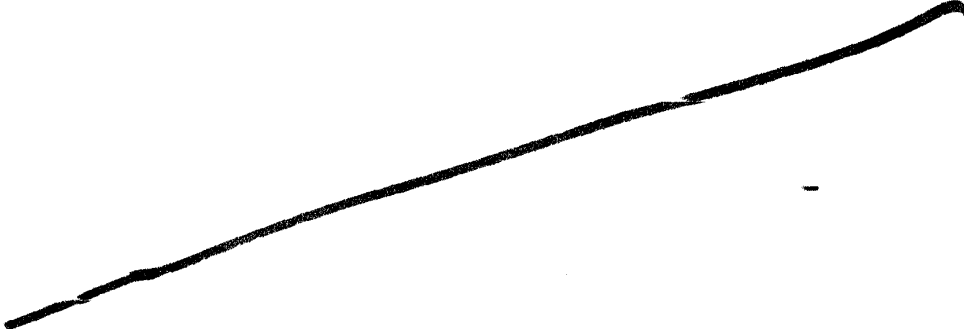
Date: 29 November 2000

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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



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Section K. Records Audit

Section L. Certification and Reporting

received  
2/01/01 DD

**Birmingham**  
3221 Third Avenue South  
Birmingham, Alabama 35222-1707  
205-251-4191



**Montgomery**  
543 South Hull Street - P.O. Box 4600  
Montgomery, Alabama 36103-4600  
334-263-5745

January 30, 2001

Deborah J. Denson, NLCP Technical Analyst  
National Laboratory Certification Program  
Research Triangle Institute  
3040 Cornwallis Road, Building 3  
Research Triangle Park, North Carolina 27709-2194

Dear Ms. Denson:

Thank you for allowing me to contact you today with my questions concerning

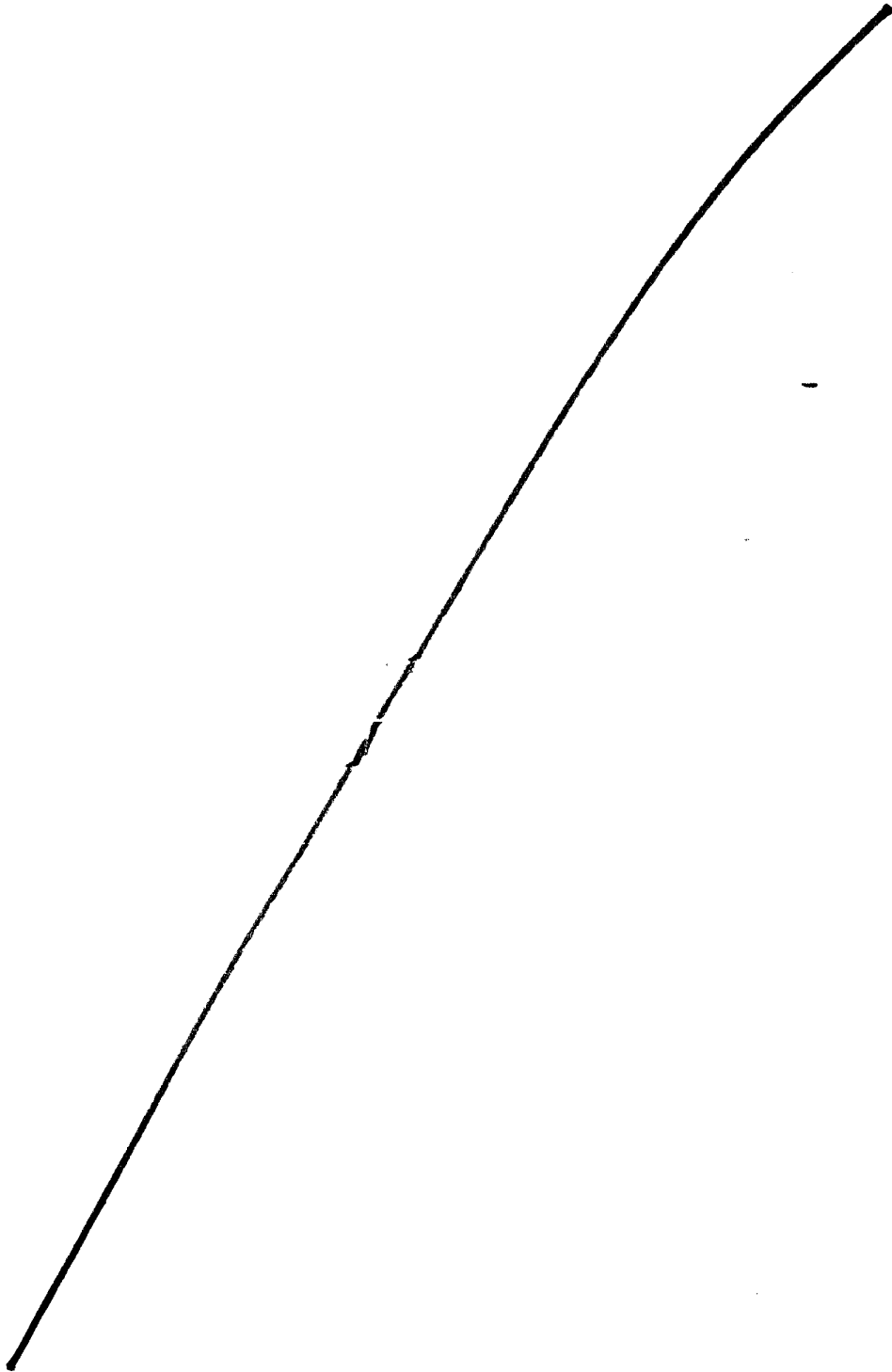
Enclosed are Alabama Reference Laboratories' response and related documents concerning the report received from NLCP for the recent specimen validity testing inspection of our laboratory. If you wish anything further, please call me at (800) 543-4931.

Sincerely,

A handwritten signature in cursive script that reads "C. Thomas Huber".

C. Thomas Huber, Ph.D., DABCC,  
Responsible Person and Director of Toxicology

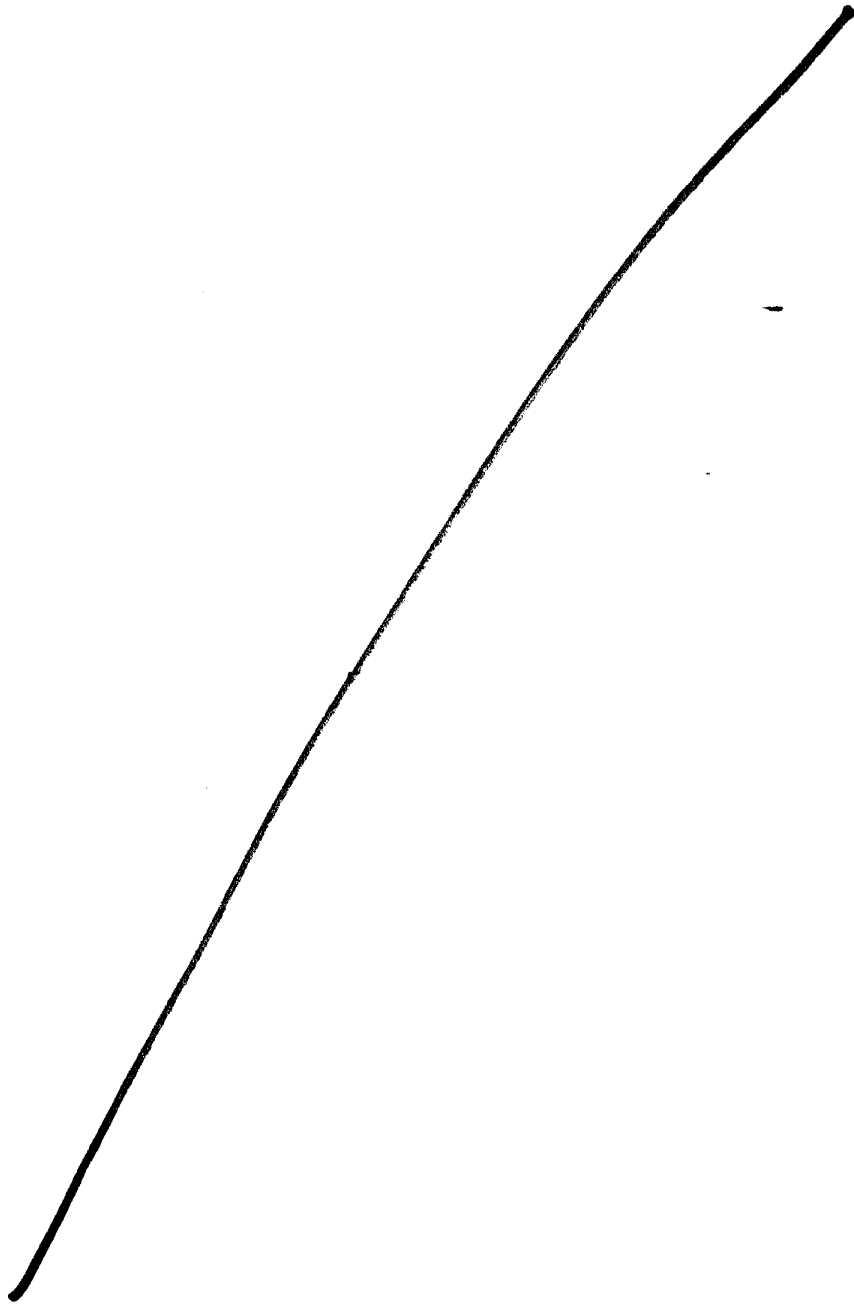
Response to Specimen Validity Testing Inspection Report

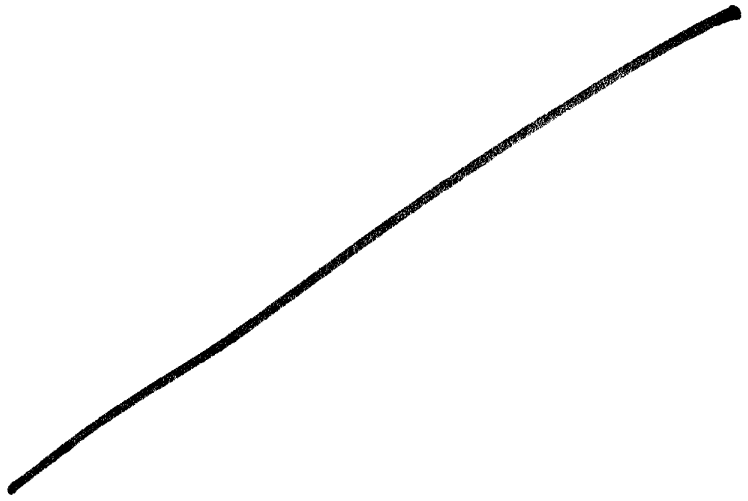


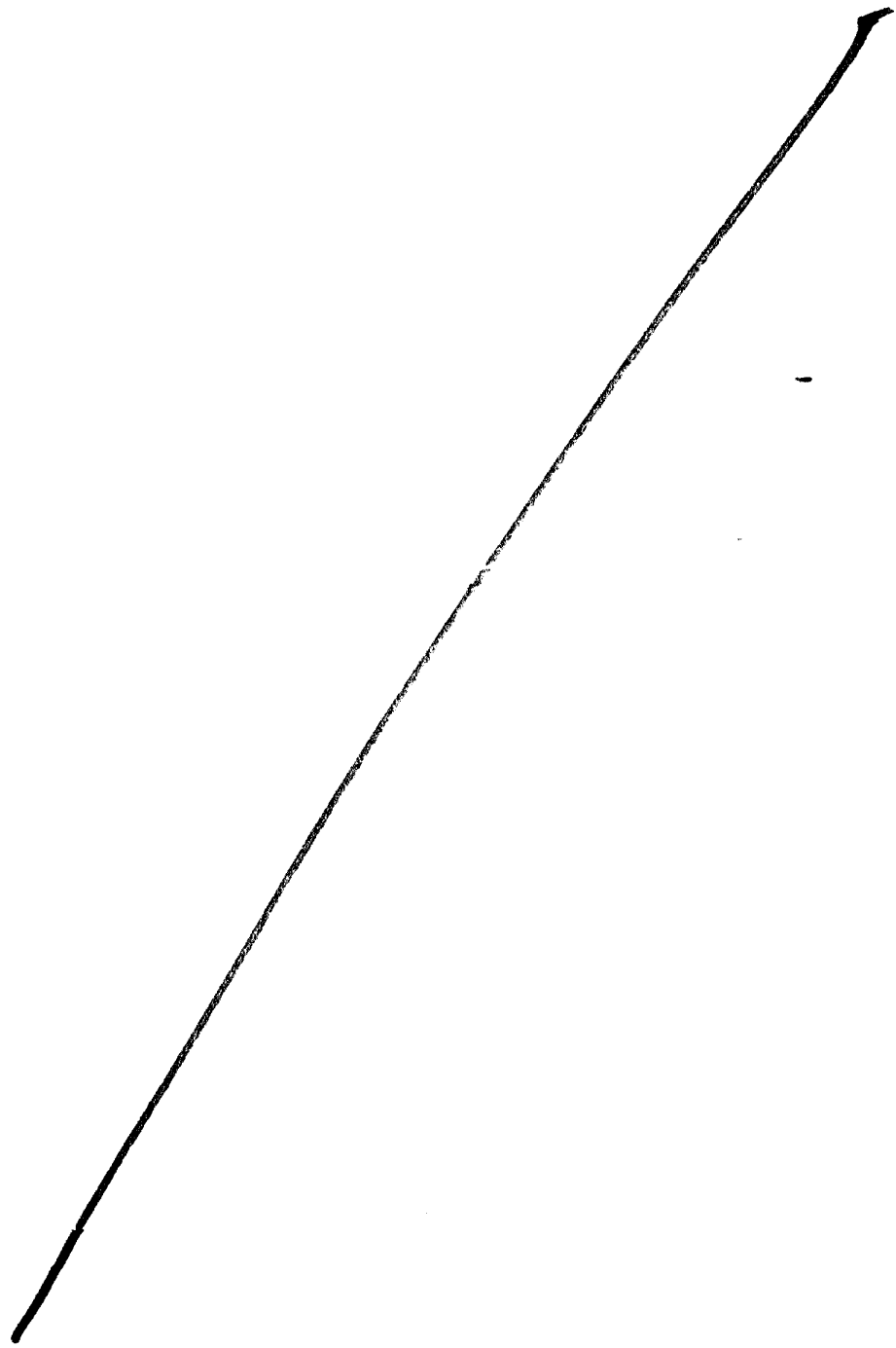


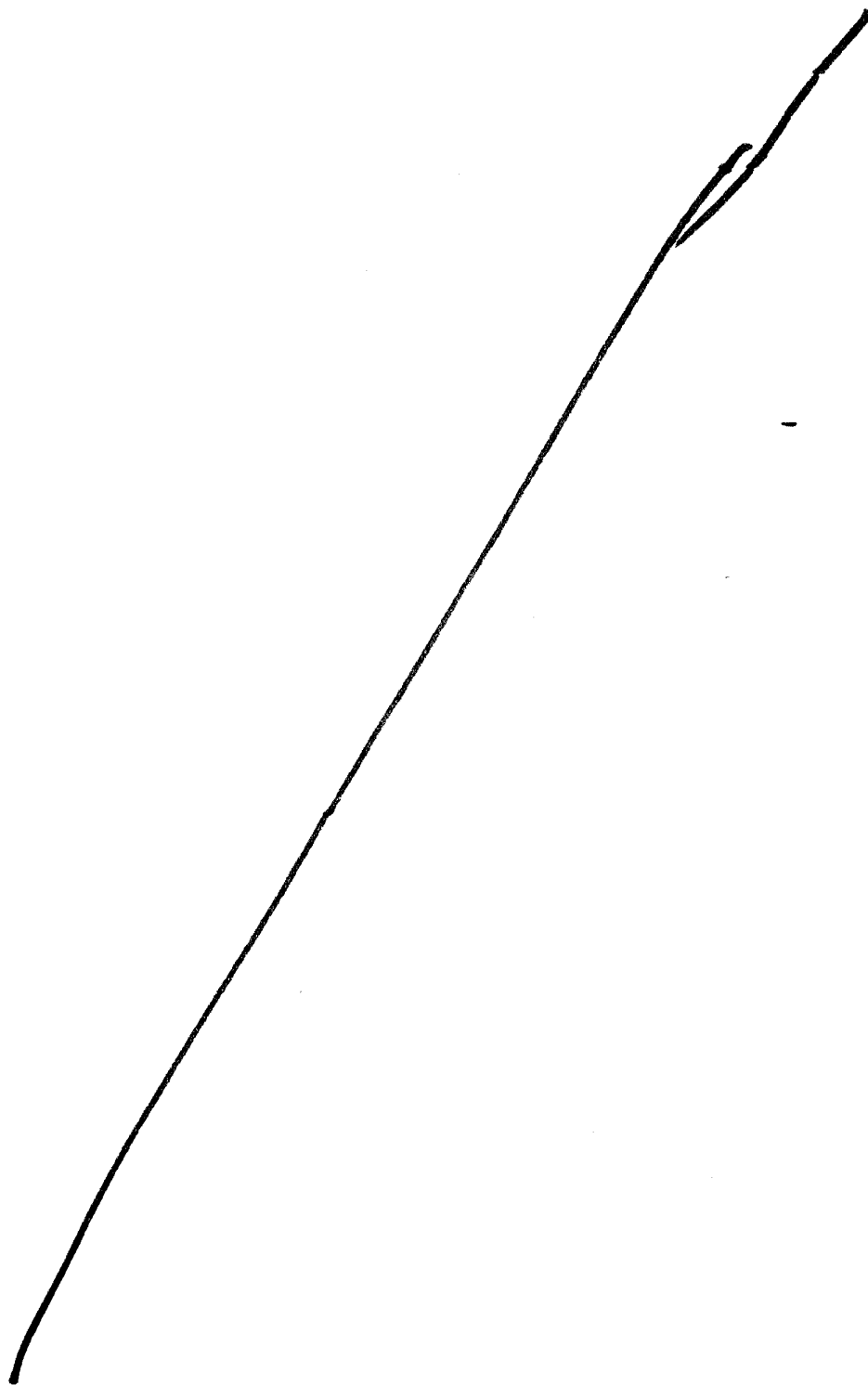
January 25, 2001

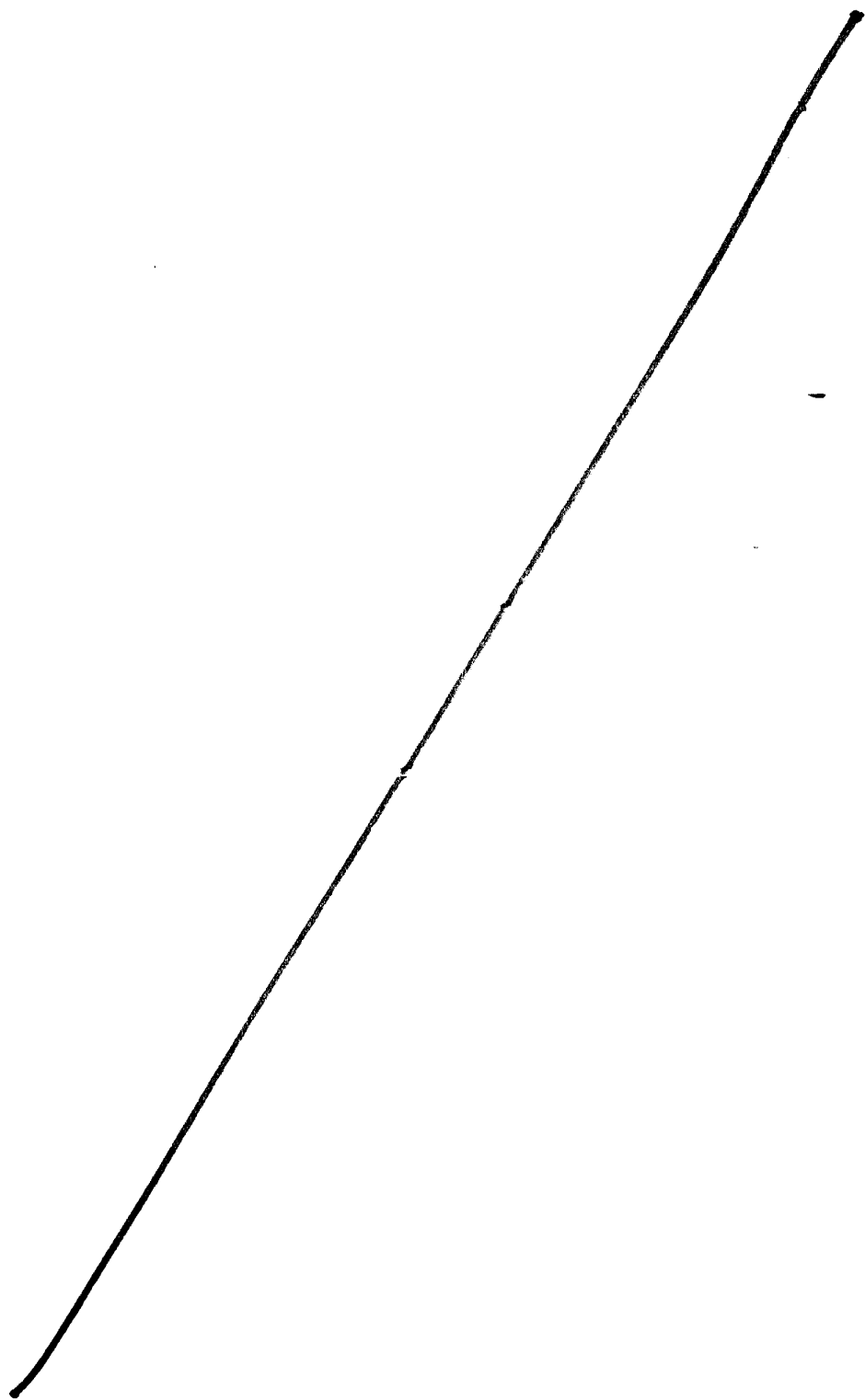
Response to Specimen Validity Testing Inspection Report

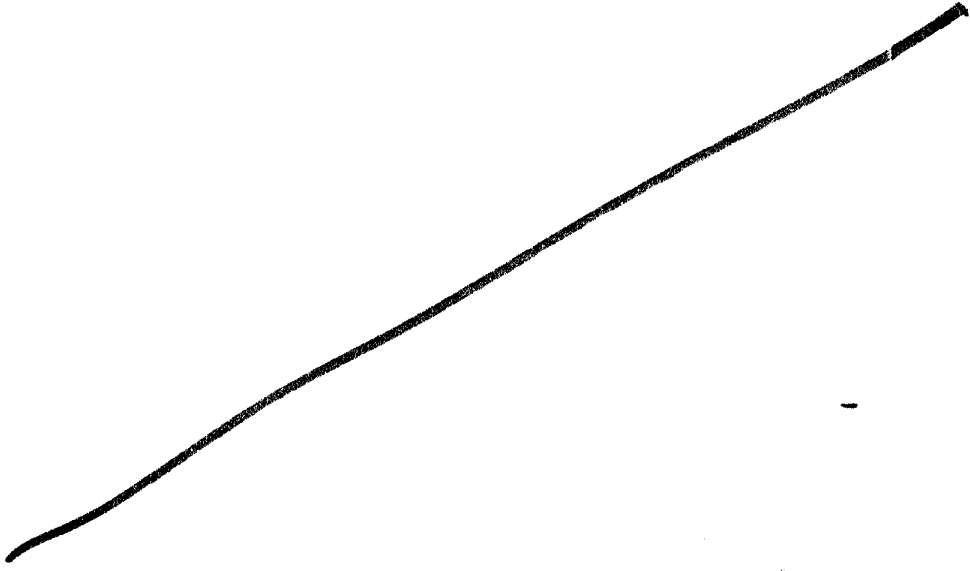


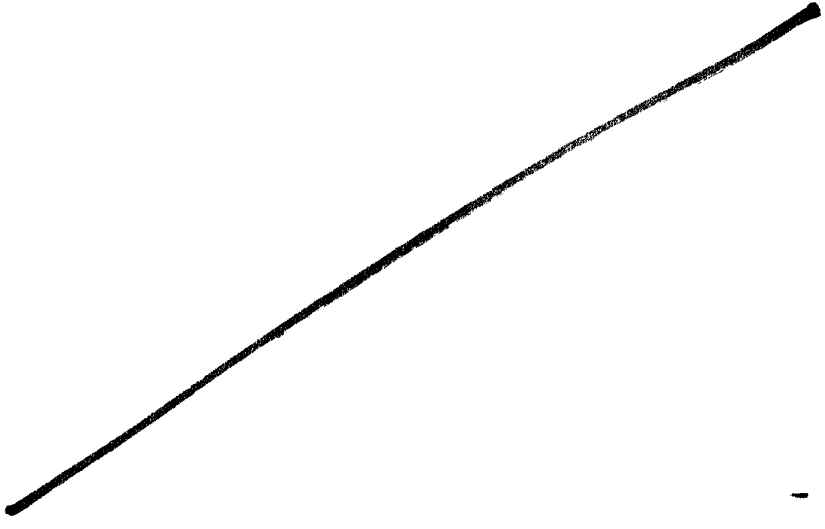














# RESEARCH TRIANGLE INSTITUTE

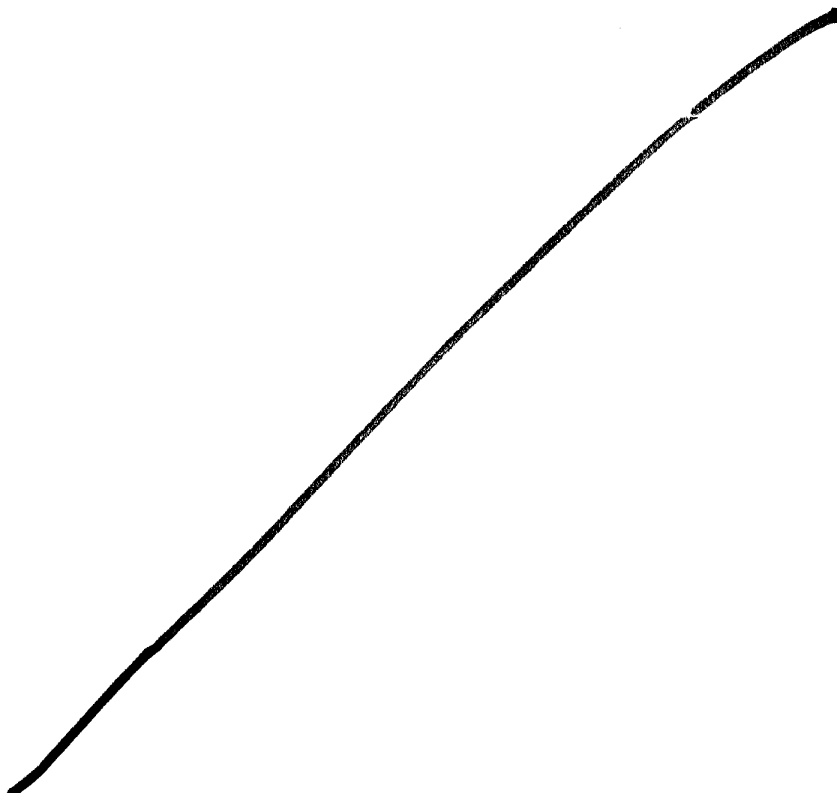
National Laboratory Certification Program

February 8, 2001

0400  
Dr. C. Thomas Huber  
Alabama Reference Laboratories, Inc.  
543 South Hull Street  
Montgomery, AL 36103

Dear Dr. Huber:

We have reviewed the material provided in your correspondence of January 30, 2001 submitted in response to issues raised during the November 29, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of December 27, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address the issues raised. The following is a review of the material submitted:



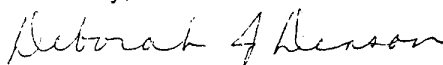


Dr. Huber  
February 8, 2001  
Page 2 of 2

Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that its 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,



Deborah J. Denson  
NLCP Technical Analyst

cc: Project Files/SVT400